DOCKET

No. 08-905

Title:	Merck & Co., Inc., et al., Petitioners
	v.
	Richard Reynolds, et al.
Docketed:	January 21, 2009
Lower Ct:	United States Court of Appeals for the Third Circuit
Case Nos.:	(07-2431, 07-2432)
Decision Date:	September 9, 2008
Rehearing Denied:	October 17, 2008

Questions Presented

Date	Proceedings and Orders
Jan 15 2009	Petition for a writ of certiorari filed. (Response due February 20, 2009)
Feb 13 2009	Order extending time to file response to petition to and including March 23, 2009.
Mar 23 2009	Brief of respondents Richard Reynolds, et al. in opposition filed.
Apr 7 2009	Reply of petitioners Merck & Co., Inc., et al. filed.
Apr 8 2009	DISTRIBUTED for Conference of April 24, 2009.
May 5 2009	DISTRIBUTED for Conference of May 21, 2009.
May 11 2009	Supplemental brief of petitioners Merck & Co., Inc., et al. filed. (Distributed)
May 13 2009	Supplemental brief of respondents Richard Reynolds, et al. filed. (Distributed)
May 26 2009	Petition GRANTED.
Jun 17 2009	The time within which to file the joint appendix and petitioners' brief on the merits is extended to and including August 10, 2009.
Jun 17 2009	The time within which to file respondents' brief on the merits is extended to and including October 16, 2009.
Jul 20 2009	Blanket consent to the filing of amicus briefs, in support of either party or of neither party, received from counsel for petitioner and counsel for respondent.
Aug 10 2009	Joint appendix filed. (Jt. appendix in two volumes). Statement of costs received.
Aug 10 2009	Brief of petitioners Merck & Co., Inc., et al. filed.
Aug 17 2009	Brief amicus curiae of Pharmaceutical and Research Manufacturers of America filed.
Aug 17 2009	Brief amicus curiae of DRI - the Voice of the Defense Bar filed.
Aug 17 2009	Brief amicus curiae of Washington Legal Foundation filed.
Aug 17 2009	Brief amicus curiae of Securities Industry and Financial Markets Association filed.
Aug 17 2009	Brief amicus curiae of Chamber of Commerce of the United States of America filed.
Sep 28 2009	SET FOR ARGUMENT ON Monday, November 30 2009.
Sep 29 2009	CIRCULATED
Oct 14 2009	The time within which to file respondents' brief on the merits is further extended to and including October 19, 2009.
Oct 19 2009	Brief of respondents Richard Reynolds, et al. filed. (Distributed)
Oct 26 2009	Brief amicus curiae of United States filed. (Distributed).
Oct 26 2009	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
Oct 26 2009	Brief amicus curiae of National Coordinating Committee for Multiemployer Plans filed. (Distributed)

Oct 26 2009	Brief amicus curiae of National Association of Shareholder and Consumer Attorneys filed. (Distributed)
Oct 26 2009	Brief amici curiae of Change to Win and The Change to Win Investment Group filed. (Distributed)
Oct 26 2009	Brief amici curiae of Ohio, et al. filed. (Distributed)
Oct 26 2009	Brief amici curiae of Connecticut Retirement Plans and Trust Funds, et al. filed. (Distributed)
Oct 26 2009	Brief amicus curiae of Council of Institutional Investors filed. (Distributed)
Oct 26 2009	Brief amici curiae of Dr. Harlan M. Krumholz and Dr. Joseph S. Ross filed. (Distributed)
Oct 26 2009	Brief amici curiae of AARP, et al. filed. (Distributed)
Oct 26 2009	Brief amici curiae of Faculty at Law and Business Schools filed. (Distributed)
Nov 9 2009	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED.
Nov 10 2009	Record received from U.S.C.A. for Third Circuit. (1 box)
Nov 12 2009	Reply of petitioners Merck & Co., Inc., et al. filed. (Distributed)
Nov 12 2009	Record for U.S.D.C. for the District of New Jersey is Electronic.
Nov 24 2009	Letter from counsel for amici Dr. Harlan M. Krumholz and Dr. Joseph S. Ross proposing to lodge copies of a transcript of Dr. Krumholz's testimony cited to in petitioners' reply brief on the merits.
Nov 30 2009	Argued. For petitioners: Kannon K. Shanmugam, Washington, D.C. For respondents: David C. Frederick, Washington, D.C.; and Malcolm L. Stewart, Deputy Solicitor General, Department of Justice, Washington, D.C. (for United States, as amicus curiae.)

PETITION FOR WRIT OF CERTIORARI

No. _____ 08-9 JAN 5 2009

IN THE OFFICE OF THE CLERK
Supreme Court of the United States

MERCK & CO., INC., *ET AL.*,

Petitioners,

v.

RICHARD REYNOLDS, STEVEN LEVAN, JEROME HABER, *ET AL.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITION FOR A WRIT OF CERTIORARI AND APPENDIX

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January 15, 2009

QUESTION PRESENTED

Did the Third Circuit err in holding, in accord with the Ninth Circuit but in contrast to nine other Courts of Appeals, that under the "inquiry notice" standard applicable to federal securities fraud claims, the statute of limitations does not begin to run until an investor receives evidence of scienter without the benefit of any investigation?

RULE 14.1(b) STATEMENT

The petitioners, who were the defendants-appellees below, are Merck & Co., Inc. and certain of its current and former officers and directors: Raymond V. Gilmartin, Kenneth C. Frazier, Richard C. Henriques, Jr., Peter S. Kim, Judy C. Lewent, Alise S. Reicin, Edward M. Scolnick, Lawrence A. Bossidy, William G. Bowen, Johnnetta B. Cole, William B. Harrison, Jr., William N. Kelley, Heidi G. Miller, Thomas E. Shenk, Anne M. Tatlock, Samuel O. Thier, David Anstice, Richard T. Clark, Celia Colbert, Linda M. Distlerath, Caroline Dorsa, Bernard J. Kelley, Per G.H. Lofberg, Per Wold-Olsen, and Lloyd C. Elam.

The respondents, who were the plaintiffs-appellants below, are lead plaintiffs Richard Reynolds, Steven LeVan, Marc Nathanson, and Jerome Haber, and additional plaintiffs Loren Arnoff, Robert Edwin Burns, Jan Charles Finance S.A., Martin Mason, Frank H. Saccone, Charlotte Savarese, Joe Savarese, Joseph Goldman, Sherri B. Knuth, Joseph S. Fisher, M.D., Naomi Raphael, Rhoda Kanter, Park East, Inc., and Union Asset Management Holding AG, on behalf of its funds.

RULE 29.6 STATEMENT

Petitioner Merck & Co., Inc. states that it has no parent corporation and that no publicly held corporation owns more than 10% of its stock.

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The opinion of the Court of Appeals is reported at 543 F.3d 150 and is reprinted in the Appendix to this petition. (App. 1a-61a.) The opinion of the district court is reported at 483 F. Supp. 2d 407. (App. 62a-99a.) The order denying petitioners' motion for rehearing *en banc* was not reported. (App. 100a-101a.)

JURISDICTION

The judgment of the Court of Appeals was entered on September 9, 2008. The order denying petitioners' motion for rehearing *en banc* was entered on October 17, 2008. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

The question presented by this petition involves 28 U.S.C. § 1658(b), entitled "Time limitations on the commencement of civil actions arising under Acts of Congress," which provides in relevant part:

> (b) [A] private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws, as defined in section 3(a)(47) of the Securities Exchange Act of 1934 (15 U.S.C. § 78c (a)(47)), may be brought not later than the earlier of—
>
> (1) 2 years after the discovery of the facts constituting the violation; or

(2) 5 years after such violation.

INTRODUCTION

This case presents the important and recurring question of when the statute of limitations begins to run on a federal securities fraud claim. Although there is broad agreement that the limitations period commences once an investor is placed on "inquiry notice" of its claim, the Courts of Appeals construe "inquiry notice" in inconsistent and irreconcilable ways, yielding conflicting and unpredictable results. In the last year alone, two Courts of Appeals – the Ninth Circuit, and the Third Circuit, in its opinion below – have further widened this split. Given the abiding and increasing uncertainty in this area of the law, this Court should clarify the proper measure of the statute of limitations for securities fraud claims, an issue it has not revisited since its decision in *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991), nearly two decades ago.

In *Lampf*, this Court held that the statute of limitations for securities fraud claims should be governed by a uniform, nationwide standard. *See Lampf*, 501 U.S. at 364. Under *Lampf*, which was ratified and codified by Congress, a federal securities fraud claim brought under section 10(b) of the Securities Exchange Act of 1934 (and Securities and Exchange Commission Rule 10b-5 promulgated thereunder) must be brought within two years "after the discovery of the facts constituting the violation." *See* 28 U.S.C. § 1658(b). Every Court of Appeals to consider this provision has held that the statute of limitations may be triggered by "inquiry notice" as well as actual notice. Under the inquiry notice standard

as typically applied, a plaintiff, once placed on notice of the possibility that it has been defrauded, has a duty to investigate potential claims.

Despite this general agreement, Courts of Appeals are increasingly divided on when the statute of limitations starts to run under an "inquiry notice" standard. Before the past year, Courts of Appeals generally followed one of two inconsistent approaches. Some Courts of Appeals held that the statute of limitations begins to run from the moment a potential plaintiff possesses enough facts to suggest the *possibility* that it has been defrauded. Other Courts of Appeals, in contrast, held that the statute of limitations begins to run on what might be a significantly later date: when a reasonable investor, alerted to the possibility of fraud and under a duty to investigate, would have discovered facts sufficient to bring suit.

Until recently, courts following both approaches agreed that an investor's duty to investigate potential fraud is triggered when the investor knows, or has reason to know, that a representation on which it relied was false. In the past year, however, two Courts of Appeals separately adopted yet a third interpretation of the inquiry notice standard, breaking with the other Courts of Appeals in holding that no duty to investigate arises, and the statute of limitations does not begin to run, until the plaintiff receives specific evidence of the elements of its claim without the benefit of any investigation.

In the first of these cases, *Betz v. Trainer Wortham & Co.*, 519 F.3d 863 (9th Cir. 2008), the Ninth Circuit held that the duty to investigate possi-

ble fraud is not triggered unless a plaintiff fortuitously encounters evidence that a statement was not only false, but *knowingly* false, when it was made – *i.e.*, that it was made with scienter. According to the Ninth Circuit, only then is a plaintiff obligated to inquire into whether it was the victim of fraud. *See Betz*, 519 F.3d at 873. A petition for *certiorari* is currently pending in *Betz*. *See* Petition for a Writ of Certiorari, *Trainer Wortham & Co. v. Betz*, No. 07-1489 (May 27, 2008) ("*Betz* Pet."). This Court has invited the Solicitor General to file a brief expressing the views of the United States on the petition. *See Trainer Wortham & Co. v. Betz*, 129 S. Ct. 339 (2008).

Shortly after *Betz*, the Third Circuit reached a similar holding in the present case, where respondents allege that petitioners made knowing misrepresentations regarding the safety of VIOXX® ("Vioxx"), a pharmaceutical formerly manufactured and sold by petitioner Merck & Co., Inc. ("Merck"). Respondents conducted no investigation into the possibility that Merck made such alleged misrepresentations despite (1) a public letter from the Food and Drug Administration ("FDA") addressed to Merck concerning Merck's alleged misrepresentations about the cardiovascular safety of Vioxx; (2) an article in *The New York Times* attributing to a Merck scientist an acknowledgment that Vioxx may increase the risk of heart attacks, and (3) the filing of numerous lawsuits alleging that Merck had misrepresented the cardiovascular safety of Vioxx. In reversing the District Court's dismissal of respondents' claims as time-barred, the Third Circuit – over a vigorous dissent (and, later, four votes for rehearing *en banc*) – joined

the Ninth Circuit in holding that an investor must possess evidence of scienter before a duty to investigate is triggered. Indeed, the Third Circuit went even farther than the Ninth Circuit in holding that some kind of investor reaction to the disclosed information – namely, a change in analyst ratings for a company's stock or a significant drop in its stock price – is required before a duty to inquire arises. In so holding, the Third Circuit has excused an investor from asking a single question until it has evidence not just of scienter, but of materiality and loss causation as well.

In addition to further dividing the Courts of Appeals, the new approach followed by the Third and Ninth Circuits runs contrary to the fundamental purpose of inquiry notice – to encourage the timely filing of fraud claims by placing an affirmative burden on plaintiffs to investigate potential claims. Ignoring this goal, the Third and Ninth Circuits have essentially read the "inquiry" out of inquiry notice. Where other circuits impose a duty to investigate once a plaintiff is on notice of the *possibility* of fraud, under the Third and Ninth Circuits' standard, no such duty arises unless evidence supporting specific elements of a fraud claim falls into an investor's lap.

In practice, this three-way circuit split ensures that the same claim will be time-barred in some circuits, but allowed in others. Consider the case below: in the Eleventh and Fourth Circuits, where the statute of limitations begins to run as soon as a plaintiff receives "storm warnings" of possible fraud, respondents' claims would be time-barred. *See infra* p. 25. The result would likely be the same in the Second Circuit. *See infra* pp. 25-26. But in the

Ninth Circuit after *Betz*, a court would likely agree with the analysis below and find respondents' claims timely because there was no widespread evidence of scienter more than two years before respondents filed suit. *See infra* p. 27. The fate of respondents' claims in most other circuits, meanwhile, is unknown, likely turning on factors that were never addressed by the court below. *See infra* pp. 26-27. Far from fulfilling Congress's desire for a uniform national standard governing the statute of limitations for federal securities fraud claims, these divergent outcomes encourage plaintiffs to forum-shop, burden parties with uncertainty, and leave investors unsure of their obligations to pursue potential claims.

Eighteen years after *Lampf*, there is still no consensus on when the statute of limitations begins to run on a securities fraud claim, nor is there agreement on the proper scope of a plaintiff's obligation to investigate potential fraud. Instead, an irreconcilable and growing circuit split has emerged. This Court should resolve it.

STATEMENT

This suit arises out of Merck's development and sale of the prescription pain medication Vioxx and Merck's alleged misrepresentations regarding the drug's alleged cardiovascular risks.[1]

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[1] Petitioners draw the following alleged facts from respondents' original and amended complaints, as well as public documents of which this Court may properly take judicial notice. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S.

Vioxx is a member of a class of pain medications known as non-steroidal anti-inflammatory drugs ("NSAIDs"). Most NSAIDs block two enzymes, one that helps maintain the lining of the stomach, and another that triggers pain and inflammation. Vioxx, blocking only the latter, was designed to reduce pain and inflammation without serious gastrointestinal ("GI") side effects.

In January 1999, Merck commenced a study called "VIGOR" to compare the GI effects of Vioxx with those of another NSAID, naproxen. The publicly reported results of the study indicated a lower incidence of GI events, but also a higher rate of serious cardiovascular events, in the patients taking Vioxx as compared to those taking naproxen. JA 714.[2]

There were several possible explanations for this disparity. One was that naproxen prevented blood clots, protecting patients against possible heart attacks (the "naproxen hypothesis"); another was that Vioxx increased the possibility of blood clots, raising the risk of cardiovascular events. In its announcement of the VIGOR results, Merck favored the naproxen hypothesis: "[S]ignificantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation. This effect on these events had not been ob-

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308, 127 S.Ct. 2499, 2509 (2007). As it did below, Merck accepts these facts as true only for purposes of this filing.

[2] "JA" refers to the Joint Appendix that was filed by the parties in the Third Circuit.

served previously in any clinical studies for naproxen." JA 765.

A. Merck Advocates the Naproxen Hypothesis.

In April 2000, Merck publicly stated its belief that the difference in thrombotic event rates between Vioxx and naproxen in the VIGOR trial was likely due to the naproxen hypothesis. *See* JA 2288. This interpretation of the VIGOR data sparked a vigorous public debate concerning the naproxen hypothesis and alternative explanations for the VIGOR results. For example, on April 27, 2000, Reuters published an article in which it reported that analysts were "not reassured by Merck's suggestion that naproxen conferred protection against heart attacks and strokes" and quoted Roche Holdings Ltd., a manufacturer of naproxen, as stating: "To our knowledge, naproxen does not prevent heart attack or stroke." *Id.*

B. The FDA Issues a Warning Letter to Merck Concerning Its Alleged Misrepresentations Regarding the Cardiovascular Safety of Vioxx.

On September 17, 2001, the FDA issued a Warning Letter to Merck stating that Merck had "engaged in a promotional campaign for Vioxx that minimize[d] the potentially serious cardiovascular findings that were observed in the [VIGOR] study, and thus, misrepresent[ed] the safety profile for Vioxx." JA 713. The FDA stated that "[a]lthough the exact reason for the increased rate of [myocardial infarctions ('MIs')] observed in the Vioxx treatment group is unknown," Merck had "selectively" pre-

sented the hypothesis that the VIGOR results were due to the cardioprotective effects of naproxen without disclosing that the naproxen hypothesis "has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties." *Id.* According to respondents' own allegations, "FDA Warning Letters are sent only to address serious circumstances." JA 1280 ¶ 79.

The Warning Letter was published on the FDA's public website on September 21, 2001. *See* App. 72a. Upon its release, the Warning Letter received immediate and widespread media and analyst coverage. *See* App. 72a-75a. For example, on September 25, 2001, *The Wall Street Journal* reported, "Federal regulators warned Merck & Co. for improper marketing of its blockbuster arthritis drug Vioxx, saying the company had misrepresented the drug's safety profile and minimized its potential risks. . . . While the FDA sends out dozens of routine citations annually, it issues only a handful of these more-serious warning letters each year." JA 2361. Similarly, on September 26, 2001, *The New York Times* reported, "The [FDA] has ordered Merck & Company to cease promotions intended to persuade doctors to prescribe its arthritis painkiller Vioxx, saying the promotions minimize potential risks." JA 2363.

The publication of the FDA Warning Letter was immediately followed by a sharp decline in the price of Merck's stock. On September 25, 2001, Reuters reported that "[s]hares of Merck & Co. fell on Tuesday after U.S. regulators accused the firm of making unsubstantiated claims about its hot-selling arthritis drug Vioxx and downplaying a possible risk of heart

attack from taking the medicine." JA 2357. Between September 20, 2001 and September 25, 2001, Merck's stock price declined by $4.40, or 6.6%. JA 1773.

On October 9, 2001, *The New York Times* published an article that discussed the FDA Warning Letter in which it quoted petitioner Dr. Edward Scolnick, then president of Merck Research Laboratories, as stating that "'[t]here are two possible interpretations'" of the VIGOR study data: "'Naproxen lowers the heart attack rate, or Vioxx raises it.'" JA 2367. From January 1, 2001, to October 9, 2001, as the public debate concerning the naproxen hypothesis intensified, Merck's stock price declined by $24.32, or 27.4%. JA 1770-73.

C. Lawsuits are Filed Alleging that Merck Had Misrepresented the Cardiovascular Risks of Vioxx.

On May 29, 2001, the first Vioxx-related product liability class action was filed in the United States District Court for the Eastern District of New York. JA 1747-61. The plaintiffs in that suit alleged that "Merck's own research [demonstrated that] users of Vioxx were four times as likely to suffer heart attacks as compared to [users of] other less expensive medications" but that Merck took "no affirmative steps to communicate this critical information to class members." JA 1748 ¶ 3.

Shortly after the FDA published the Warning Letter, three additional product liability and consumer fraud lawsuits were filed against Merck, all alleging that Merck had misrepresented the cardio-

vascular safety of Vioxx: (1) on September 27, 2001, a consumer fraud class action was filed in New Jersey state court, alleging that "Merck [had] omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Vioxx, including . . . cardiovascular problems," JA 1557 ¶ 32; (2) on September 28, 2001, an action asserting both product liability and fraud claims was filed in Utah state court, alleging that Merck had "misrepresented that Vioxx was a safe and effective way to relieve osteoarthritis, management of acute pain in adults, and treatment of menstrual pain, when in fact the drug causes serious medical problems such as an increased risk of cardiovascular events," JA 1574; and (3) on October 1, 2001, an action asserting product liability claims was filed in Alabama state court, alleging that Merck failed to disclose that "Vioxx causes heart attacks," JA 1611 ¶ 19.

D. Merck Withdraws Vioxx from the Market.

On September 30, 2004, Merck announced that it was voluntarily withdrawing Vioxx from the market based on new results from an ongoing study (named "APPROVe") showing an "increased risk of confirmed cardiovascular events beginning after 18 months" of continuous use. JA 583-84.

E. Respondents File Suit.

On November 6, 2003, respondents filed the first Vioxx-related securities fraud class action in the United States District Court for the Eastern District of Louisiana, alleging that petitioners had misrepresented "the cardiovascular risks associated with

VIOXX." JA 1224. Numerous additional Vioxx-related securities actions were filed thereafter. On February 23, 2005, the Judicial Panel on Multidistrict Litigation ("JPML") issued a Transfer Order, transferring all Vioxx-related securities, derivative and ERISA actions pending in the federal courts to the United States District Court for the District of New Jersey (the "District Court") "for coordinated or consolidated pretrial proceedings." JA 442-43. On May 5, 2005, the District Court "consolidated for all purposes" all pending and subsequently-filed Vioxx-related securities actions. JA 445-63.

On June 14, 2005, respondents filed their operative Complaint. Like the November 2003 complaint, the Complaint asserts various claims under the Securities Act of 1933 and the Securities Exchange Act of 1934, based on allegations that "Defendants misrepresented the [cardiovascular] safety profile of Vioxx." JA 470 ¶ 10.

F. The District Court Dismisses Respondents' Claims as Time-Barred.

Defendants moved to dismiss respondents' claims, arguing in part that they were barred by the two-year statute of limitations. *See* 28 U.S.C. § 1658(b).[3] In analyzing this argument, the District

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[3] Under 28 U.S.C. § 1658(b), securities fraud claims must be brought the earlier of (a) two years after the discovery of the facts constituting the violation or (b) five years after the violation. Petitioners did not make any argument below concerning the statute of repose.

Court applied the Third Circuit's two-step inquiry notice test.

Under this test, a defendant must first establish that, as of a particular date, there existed "'storm warnings'" sufficient to alert a reasonable investor of ordinary intelligence to possible wrongdoing on the part of the defendants. *Benak v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 400 (3d Cir. 2006) (quoting *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1325 (3d Cir. 2002)). Under Third Circuit law, "storm warnings may take numerous forms" and include any information that would alert a reasonable investor to the possibility that the defendants engaged in "the general fraudulent scheme" alleged in the complaint. *In re NAHC*, 306 F.3d at 1326 & n.5. If the defendants establish the existence of "storm warnings," then the second part of the inquiry notice test is reached, and "'the burden shifts to the plaintiff[] to show that [it] exercised reasonable due diligence and yet w[as] unable to discover [its] injuries.'" *Benak*, 435 F.3d at 400 (quoting *Mathews v. Kidder, Peabody & Co., Inc.*, 260 F.3d 239, 252 (3d Cir. 2001)). "[I]f storm warnings existed, and the [plaintiff] chose not to investigate, [it] will [be] deem[ed] . . . on inquiry notice of [its] claims" as of the date the "storm warnings" first appeared. *Id.* at 401 (quoting *Mathews*, 260 F.3d at 252 n.16).

Respondents failed to conduct any investigation into possible fraud by Merck. App. 98a. Thus, petitioners' statute of limitations argument presented a single legal question: when did public information regarding Merck's statements about the cardiovascular risks of Vioxx create "storm warnings," giving

rise to respondents' duty to investigate the possibility of fraud? *See* App. 83a-84a.

Answering this question, the District Court held that there were clear "storm warnings" of the possibility that petitioners had misrepresented Vioxx's cardiovascular safety by October 9, 2001 – the date on which *The New York Times* published the article in which petitioner Dr. Scolnick was reported as stating that Vioxx "may raise the risk of heart attack or other thrombotic event." App. 84a-90a. It characterized the "mix of information" available to investors by that date as "more akin to thunder, lightning and pouring rain than subtle warnings of a coming storm." App. 94a.

Moving to the second step in the inquiry notice analysis, the District Court held that, because respondents did "not argue[] that they conducted a diligent investigation" within two years of October 9, 2001, and because "nothing in the Complaint demonstrate[d] that they were unable to uncover pertinent information during the limitations period," respondents were on inquiry notice of their claims as of October 9, 2001, at the latest – more than two years before they filed suit on November 6, 2003. App. 98a. Accordingly, the District Court dismissed respondents' claims as time-barred. App. 98a-99a.

G. The Third Circuit Reverses.

The Third Circuit reversed, purporting to employ the same two-step inquiry notice test utilized by the District Court. In doing so, the Third Circuit reiterated that the first step in the analysis is an objective assessment of "whether the defendant had met

its burden to show the existence of storm warnings." App. 24a-25a (internal quotation marks omitted). The second step, the Third Circuit confirmed, was an inquiry, "both subjective and objective, into whether the plaintiffs had met their burden to show that they exercised reasonable diligence and yet were unable to discover their injuries." App. 25a (internal quotation marks omitted).

In its analysis, the Third Circuit indicated that heavy, if not dispositive, weight should be accorded to the reactions of analysts and the stock market to the alleged storm warnings cited by petitioners. Relying in part on authority from the Ninth Circuit, the Third Circuit stated that these factors are critical because "[d]iscovery of [plaintiffs' losses] leads almost immediately to discovery" of defendant's misrepresentations. App. 37a-38a (internal quotation marks omitted). Thus, "[i]f the disclosure of certain information has no effect on stock prices, it follows that the information disclosed was immaterial as a matter of law." App. 37a (internal quotation marks omitted).

Applying this standard, the Third Circuit held that the statute of limitations did not begin to run unless and until respondents had knowledge that Merck acted with scienter – that is, that Merck's support for the naproxen hypothesis was not held "in earnest." App. 33a. Thus, the Court rejected the proposition that any of the following incidents – taken alone or together – triggered respondents' duty to investigate a possible fraud claim: (1) the robust public debate concerning Merck's interpretation of the VIGOR data, which included several reporters and analysts who questioned Merck's support for the

naproxen hypothesis; (2) the widely publicized Warning Letter, which concerned Merck's alleged misrepresentations regarding the cardiovascular safety of Vioxx; (3) Dr. Scolnick's statement that Vioxx may cause heart attacks; and (4) numerous lawsuits alleging that Merck misrepresented the cardiovascular safety of Vioxx. App. 46a-47a.

According to the Third Circuit, its conclusion was reinforced by the fact that selected analysts and the stock market reacted moderately to these events.[4] App. 44a-45a (stating that the price of Merck stock dipped only "slightly" following publication of the FDA Warning Letter); App. 46a (finding "notable" the fact that there was no "significant movement" in the price of Merck stock following the October 9, 2001 article in *The New York Times*). Thus, the court effectively held that no duty to investigate arose unless and until the stock market reacted to a degree that reflected disclosure of a full-scale fraud.

In a vigorous dissent, Judge Roth argued that any reasonable investor would have investigated *possible* fraud in the face of the "storm warnings" discussed above. The dissent emphasized that knowledge of all of the "details or narrow aspects" of the alleged fraud is not necessary before a duty to investigate arises; instead, knowledge of the possibility that respondents had engaged in the "general

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[4] The Third Circuit ignored the fact that the price of Merck stock declined sharply in the months leading up to October 9, 2001. *See* App. 60a-61a n.21 (Roth, J., dissenting).

fraudulent scheme" alleged in the complaint is enough. App. 50a.

According to the dissent, the FDA Warning Letter alone was sufficient to alert respondents to this possibility because it "clearly and explicitly reprimanded Merck" for its "deceptive and misleading conduct" regarding the cardiovascular risks of Vioxx. App. 51a-54a. The dissent also found significant the filing of numerous lawsuits specifically alleging that Merck had omitted, suppressed, or concealed material facts concerning the cardiovascular safety of Vioxx. App. 57a-58a. The dissent thus agreed with the District Court that respondents' claims were time-barred because respondents failed to investigate in response to clear storm warnings suggesting the possibility of fraud.[5]

Petitioners timely filed a petition for rehearing *en banc*, which was denied by a six-to-four vote. App. 100a-101a.

REASONS FOR GRANTING THE WRIT

This Court should grant *certiorari* to address a central and recurring question of federal securities law: when does the statute of limitations begin to

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[5] The dissent analogized this case to the plot of Hans Christian Anderson's fairytale "The Emperor's New Clothes," arguing that the fact that the price of Merck stock did not plummet following publication of the Warning Letter indicated not that the emperor "was not walking down the street with no clothes on," but only that "analysts saw the emperor's new clothes as Merck described them – not as reality presented." App. 60a (Roth, J., dissenting).

run on a claim brought under section 10(b), and what is a plaintiff's obligation to investigate potential fraud? In the eighteen years since this Court established a "uniform" statute of limitations in *Lampf*, the Courts of Appeals have addressed this issue in sharply divergent ways. Review by this Court is needed to resolve this widening split, which leads to disparate results in an area of national importance.

I. The Third Circuit Has Exacerbated a Growing Circuit Split on the Proper Start Date for the Statute of Limitations for Claims Brought Under Section 10(b).

The Courts of Appeals are sharply divided on when the statute of limitations begins to run on securities fraud claims and the scope of a plaintiff's duty to investigate whether it has been the victim of securities fraud. The result is widespread inconsistency among the circuits, leading to irreconcilable outcomes on similar sets of facts. In the decision below, the Third Circuit deepened this split by joining the Ninth Circuit in adopting a test that thwarts the goals of the inquiry notice standard.

A. The Courts of Appeals Employ Three Sharply Divergent Tests to Determine When the Statute of Limitations Begins to Run.

All but two of the Courts of Appeals have explicitly addressed the appropriate standard to be applied in determining whether the statute of limitations has run on securities fraud claims. "[E]very circuit to have addressed the issue since *Lampf* has held that inquiry notice is the appropriate standard." *See*

Betz, 519 F.3d at 874 (internal quotation marks omitted). These holdings have effectively been endorsed by Congress.[6]

Generally, in determining whether a plaintiff was on notice of its claim, the circuits employ a two-step test. The first step typically assesses whether a plaintiff was alerted to the "possibility" that it had been defrauded. *See, e.g.*, *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1204 (10th Cir. 1998). The second considers when, in the exercise of reasonable diligence, the plaintiff could have discovered the facts underlying its claim. *See, e.g.*, *id.* at 1205. Despite this ostensible agreement, the circuits differ on two central questions, resulting in at least three distinct approaches and often leading to incongruous results. *See id.* at 1200 ("The circuits are not consistent, however, in their determination of exactly when the [statute of limitations] begins to run.").

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[6] Congress enacted the current limitations period in 2002 as part of the Sarbanes-Oxley legislation. *See* Pub. L. No. 107-204, Title VIII, § 804, 116 Stat. 745, 801 (2002). In doing so, Congress extended the statute of limitations from one year to two years and the period of repose from three years to five years, but "opted for [substantive] language identical to the language previously in effect." *Betz*, 519 F.3d at 875. The inquiry notice standard was well-established when Congress acted in 2002, and when "judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its . . . judicial interpretations as well." *See Bragdon v. Abbott*, 524 U.S. 624, 645 (1998). This canon has been specifically applied to actions brought under § 10(b). *See Merrill Lynch, Pierce, Fenner & Smith v. Dabit*, 547 U.S. 71, 85-86 (2005); *Merrill Lynch, Pierce, Fenner & Smith v. Curran*, 456 U.S. 353, 381 n.66 (1982).

The first question that divides the circuits is the precise time at which the statute of limitation begins to run under an inquiry notice standard. Some Courts of Appeals hold that the statute of limitations begins to run the moment the plaintiff is first alerted to "storm warnings" suggesting the possibility of fraud – that is, when a defendant satisfies the first step in the inquiry notice analysis. (*See infra* pp. 20-21.) Other circuits, however, hold that start date for the statute of limitations depends on the answer to the second step in the inquiry notice analysis; in these circuits, the statute of limitations will begin to run from the time that a plaintiff, after exercising reasonable diligence, could have discovered the facts underlying its claim. Courts holding this latter view are themselves split over a second crucial aspect of the inquiry notice test. In some circuits, the statute of limitations begins to run when the plaintiff could have discovered, through a reasonable investigation, the facts underlying the fraud. (*See infra* pp. 21-23.) In others, no duty to investigate arises, and the statute of limitations does not begin to run, until a plaintiff has evidence supporting the specific elements of its claim. (*See infra* pp. 23-25.) The circuits are thus divided into three divergent approaches.

1. The First Approach: Pure "Storm Warnings" (Fourth and Eleventh Circuits, and Sometimes Fifth and Eighth Circuits).

Under the first approach, embodying the most stringent test, the statute of limitations begins to run from the moment that there exist "storm warnings" of possible fraud that would prompt a reasonable investor to investigate whether it had been de-

frauded. The Eleventh and Fourth Circuits follow this approach. *See, e.g.*, *Franze v. Equitable Assurance*, 296 F.3d 1250, 1254-55 (11th Cir. 2002); *Theoharous v. Fong*, 256 F.3d 1219, 1228 (11th Cir. 2001); *GO Computer, Inc. v. Microsoft Corp.*, 508 F.3d 170, 177 (4th Cir 2007); *Brumbaugh v. Princeton Partners*, 985 F.2d 157, 162-63 (4th Cir. 1992). The Fifth and Eighth Circuits likewise start the statute of limitations clock at the first sign of "storm warnings," provided that a reasonably diligent inquiry could have uncovered the facts supporting a fraud claim within the limitations period. *See, e.g.*, *Bodenhamer v. Shearson Lehman Hutton, Inc.*, 998 F.2d 1013 (5th Cir. 1993) (unpublished table decision); *Jensen v. Snellings*, 841 F.2d 600, 606-07 (5th Cir. 1988) (starting the limitations clock on the "storm warnings" date); *Great Rivers Coop. v. Farmland Indus., Inc.*, 120 F.3d 893, 896, 899 (8th Cir. 1997) (same).

2. The Second Approach: "Storm Warnings" Plus Investigation (First, Sixth, Seventh, and Tenth Circuits, and Sometimes Second Circuit)

Under the second approach, the statute of limitations begins to run based on the second step in the inquiry notice analysis. Once a plaintiff is actually or constructively aware of the possibility it has been defrauded (through "storm warnings" or otherwise), the statute of limitations will begin to run on the date the plaintiff, exercising reasonable diligence, could have discovered the facts underlying the alleged fraud. The First, Sixth, and Tenth Circuits follow this approach. *Sterlin*, 154 F.3d at 1200-01; *see*,

e.g., *New Eng. Health Care Employees Pension Fund v. Ernst & Young LLP*, 336 F.3d 495, 501 (6th Cir. 2003); *Young v. Lepone*, 305 F.3d 1, 8-10 (1st Cir. 2002). The Seventh Circuit also follows this approach but collapses this standard into a single inquiry: when should the plaintiff, exercising reasonable diligence, have possessed sufficient facts not only to incite investigation but also to enable it to tie up loose ends and actually file suit? *See, e.g.*, *Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997).[7] The Second Circuit follows either the "pure 'storm warnings'" or "'storm warnings' plus investigation" approach, depending on whether the plaintiff fulfills its duty to investigate.[8] In each of

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[7] Further confusing this area of the law is a split within the second approach on the application of the "reasonable investigation" step in the inquiry notice analysis. For example, in the First Circuit, the plaintiff bears the burden of "showing that she fulfilled her corresponding duty of making a reasonably diligent inquiry into the possibility of fraudulent activity." *Young*, 305 F.3d at 9. The Sixth and Tenth Circuits employ a strictly objective approach, examining what information would be available to an investor who conducted a reasonably diligent investigation. *See Wyser-Pratte Mgmt. Co. v. Telxon Corp.*, 413 F.3d 553, 563 n.9 (6th Cir. 2005); *Sterlin*, 154 F.3d at 1202 n.20. The Seventh Circuit approach has both objective and subjective components, assessing what information an investor in the plaintiff's position could have uncovered had it investigated possible fraud. *See Fujisawa*, 115 F.3d at 1335.

[8] In the Second Circuit, if the plaintiff is placed on inquiry notice that a representation is false and it fails to conduct an investigation, the statute of limitations will be deemed to have run from the date the duty of inquiry arose, mirroring the first approach. *Shah v. Meeker*, 435 F.3d 244, 251 (2d Cir. 2006). If the plaintiff conducts an investigation, however, then the statute of limitations runs from the time a reasonably diligent

these circuits, a duty to investigate may arise even where – as in the present case – the information available to an investor does not suggest that a defendant's statements, if false, were made with scienter.

3. The Third Approach: Evidence of a Claim Without Investigation (Third and Ninth Circuits).

Under the third, and most lenient, approach, the statute of limitations period likewise begins to run based on the second step in the inquiry notice analysis. But unlike the second approach, the third approach holds that no duty to investigate arises – and the statute of limitations does not begin to run – unless and until the plaintiff has specific evidence of the elements of its claim, including scienter, *without* any investigation. This was the holding of the Ninth Circuit in *Betz*, which was alone among the circuits at the time it adopted this view. *See Betz*, 519 F.3d at 867-68 (Kozinski, J., dissenting from denial of rehearing *en banc*) ("The panel cites no authority supporting its curious notion that an investor isn't on inquiry notice until he has concrete proof of every element of his claim, including scienter. There is no such authority; ten circuits disagree.").

In its opinion below, the Third Circuit joined the Ninth Circuit on the periphery of inquiry notice ju-

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plaintiff would have discovered the facts underlying its securities fraud claim, mirroring the second approach. *See LC Capital Partners, LP v. Frontier Ins. Group, Inc.*, 318 F.3d 148, 154 (2d Cir. 2003).

risprudence. While keeping intact the second component of its inquiry notice test, which looks at the reasonableness of the investigation performed by the plaintiff, the Third Circuit agreed with the Ninth Circuit that no duty to inquire arises, and a court need not even *consider* what information was available to the plaintiff, until even an entirely passive plaintiff stumbles upon direct evidence of, among other things, scienter.

In fact, the Third Circuit went even farther than *Betz*, suggesting that information known to a plaintiff must be legally "material," as demonstrated by downgrades in analysts' ratings and significant declines in stock price, before a duty to investigate is triggered.[9] Thus, under the Third Circuit rule, a plaintiff is not obligated to ask a single question until it has evidence of scienter, materiality, and loss causation – that is, until it has in hand a nearly fully-formed cause of action. That holding is contrary to the law in nearly every other circuit, as well

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[9] While the Third Circuit claimed that it was not establishing a *per se* rule requiring a stock price decline (App. 47a n.16), it made clear that, under its standard, a disclosure prompting a duty to investigate will have a negative effect on the price of a company's stock – and, absent such an effect, the disclosure will not be deemed to create "storm warnings." *See* App. 37a ("If the disclosure of certain information has no effect on stock prices, it follows that the information disclosed was immaterial as a matter of law." (internal quotation marks omitted)). The dissent recognized that the majority was establishing a *de facto* requirement and disputed such a rule. *See* App. 60a ("In my view, fluctuations in stock price and analysts' ratings and projections . . . are *not* a *required* consideration" (emphasis in original)).

as the purpose of inquiry notice itself. *See, e.g.*, *Brumbaugh*, 985 F.2d at 162 ("Commencement of a limitations period need not . . . await the dawn of complete awareness."); *see infra* Part II.C.

B. The Varying Tests Employed by the Courts of Appeals Lead to Directly Contrary Results.

Under the divergent approaches discussed above, it is geography that determines whether a claim is timely. The fate of a plaintiff's claim depends not on the "uniform" national standard intended by *Lampf*, but instead upon the jurisdiction in which a plaintiff files suit or (as often happens in securities fraud cases, and as happened in the case below) the jurisdiction to which the suit is transferred as part of a multi-district litigation.

In the present case, for example, respondents' claims would almost certainly be time-barred if the JPML had transferred the action to the Eleventh or Fourth Circuits. *See, e.g.*, *Grippo v. Perazzo*, 357 F.3d 1218, 1224 (11th Cir. 2004) (holding that the statute of limitations started to run on the date that a reasonable investor would have investigated possible fraud); *Theoharous*, 256 F.3d at 1228; *Brumbaugh*, 985 F.2d at 162 ("Inquiry notice is triggered by evidence of the possibility of fraud, not by complete exposure of the alleged scam.").

The same result would likely attend in the Second Circuit, as several recent cases – with facts nearly identical to those in the case below – confirm. In stark contrast to the Third Circuit opinion below, a district court within the Second Circuit recently

found that plaintiffs were placed on inquiry notice of their securities fraud claims, which centered on the alleged adverse consequences of a pharmaceutical manufactured by the defendant, by related product liability lawsuits and newspaper articles questioning the defendant's interpretation of study data. *See In re Zyprexa Prods. Liability Litig.*, 549 F. Supp. 2d 496, 535-36 (E.D.N.Y. 2008). A recent non-precedential opinion from the Second Circuit reached the same conclusion in a case strikingly similar to *Zyprexa* and the present case. *See Masters v. GlaxoSmithKline*, 271 Fed. Appx. 46, 49 (2d Cir. 2008). Like the plaintiffs in *Zyprexa* (*see* 549 F. Supp. 2d at 541), respondents here admittedly conducted no investigation into the possibility that they had been defrauded (*see* App. 98a). Thus, if the present suit had been brought in or transferred to the Second Circuit, the statute of limitations would likely be deemed to have commenced when the duty of inquiry arose, barring respondents' claims. *See Zyprexa*, 549 F. Supp. 2d at 540; *see also Shah*, 435 F.3d at 251.

In the First, Fifth, Sixth, Seventh, Eighth, and Tenth circuits, petitioners would likely have succeeded in establishing that respondents were on notice of potential fraud more than two years before respondents filed suit. *See, e.g., Sterlin*, 154 F.3d at 1203-04 (duty to inquire arose where a single article questioned the truthfulness of defendant's representations). In most circuits, knowledge of the mere *possibility* that the defendant has made a misrepresentation is sufficient to trigger the duty to inquire. *See, e.g., Great Rivers*, 120 F.3d at 897; *LaSalle v. Medco Research, Inc.*, 54 F.3d 443 (7th Cir. 1995); *see*

also Betz Pet. at 16-19. In these circuits, therefore, the timeliness of respondents' claims would depend upon the results of a reasonably diligent investigation into the possibility that they had been defrauded – facts never considered by the Third Circuit.[10]

Only the Ninth Circuit would agree with the Third Circuit's rationale in holding that respondents' claims were timely. Applying *Betz*, the Ninth Circuit would likely find, as the Third Circuit did, that the FDA Warning Letter, the October 9, 2001 *New York Times* article, multiple product liability lawsuits, and the vigorous public debate surrounding the naproxen hypothesis did not give rise to a duty to investigate possible fraud because they did not provide any specific evidence that any of Merck's statements regarding the cardiovascular safety of Vioxx, if false, were knowingly false when made.

Thus, the patchwork of inquiry notice standards leads directly to conflicting, inconsistent, and unpredictable outcomes that invite potential plaintiffs to forum shop for the most lenient statute of limitations.

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[10] Because the circuits apply different tests in examining the "reasonable investigation" prong of the inquiry notice standard (*see supra* note 7), it is impossible to know whether they would reach the same result in this or any other case. This kind of unpredictability is the natural result of a circuit split as deep as the one presented here.

C. The Third and Ninth Circuits' Approach Thwarts the Goals of Inquiry Notice.

The rule announced by the Ninth Circuit in *Betz*, and followed by the Third Circuit below, fundamentally conflicts with the goals of inquiry notice. As conceived, inquiry notice encourages investors to "tak[e] the actions necessary to bring the fraud to light," *Brumbaugh*, 985 F.2d at 162, and "discourage[s] [them] from adopting a wait-and-see approach" to their investments, *Sterlin*, 154 F.3d at 1202. *See also Tregenza v. Great Am. Commcn's Co.*, 12 F.3d 717, 722 (7th Cir. 1993) (inquiry notice is designed to prevent "the opportunistic use of federal securities law to protect investors against market risk"); *Jensen*, 841 F.2d at 607 (the inquiry notice standard is "intended to ensure fairness to defendants against claims that have been allowed to slumber" (internal quotation marks omitted)). The approach articulated by the Third and Ninth Circuits runs afoul of these goals in several crucial respects.

First, under the Third and Ninth Circuits' standard, the "inquiry" requirement of the "inquiry notice" standard is little more than a formality. In other circuits, the touchstone of the inquiry notice analysis is precisely that – an examination of what facts a reasonable inquiry could have uncovered. The Third and Ninth Circuits, in contrast, focus on the information available to the plaintiff *without* the exercise of reasonable diligence. Unless specific evidence of scienter is one such piece of information, the inquiry notice analysis ends. Under such a test, it is unclear what purpose (if any) is served by the "inquiry" step of the inquiry notice standard. After a

plaintiff fortuitously encounters evidence of scienter, materiality and loss causation, there is not much left for it to investigate.

Second, the Third and Ninth Circuits' standard contravenes the central purpose of the inquiry notice standard by encouraging a plaintiff to disregard "storm warnings" of possible fraud. If an investor has no duty to investigate unless it happens to stumble upon evidence of specific elements of its claim, then it has every incentive to ignore the possibility of fraud to postpone the statute of limitations. *See Fujisawa*, 115 F.3d at 1337 ("It would be highly undesirable if, suspecting securities fraud, an investor could sit back and wait out the entire . . . repose period before suit."). If, on the other hand, a plaintiff is obligated to investigate "storm warnings" of fraud and is penalized for failing to conduct an investigation, investors are encouraged to root out fraud at an early date. *See id*; s*ee generally Shah*, 435 F.3d at 249-52. The standard followed by most Courts of Appeals fosters early discovery of fraud by holding that evidence of specific elements of a fraud claim is not required to trigger a duty to investigate. *See supra* pp. 20-23. Under the Third Circuit standard, in contrast, there is no reason for an investor to take any action in the face of possible fraud unless specific evidence of scienter materializes, for any failure to investigate will be forgiven *even if* such evidence could have been uncovered by a reasonably diligent investigation.

Third, while largely relieving putative plaintiffs of their obligation to investigate potential claims, the Third and Ninth Circuit standard ties defendants' hands in critical ways. For example, if evidence of

the elements of a plaintiff's claim is required before a duty to investigate is triggered, a defendant is forced to choose between a motion to dismiss on statute of limitations grounds and one based on the sufficiency of the pleading under Rule 12(b)(6). To argue the former in the Third or Ninth Circuit, a defendant must show that a plaintiff has evidence of the elements of its claim, whereas to argue the latter requires a defendant to show that a plaintiff lacks that very same evidence.[11]

Fourth, far from the original intent of inquiry notice, the standard adopted by the Third and Ninth Circuit sharply restricts – if not abolishes altogether – the two-year statute of limitations in securities fraud cases.[12] Under this standard, the only claim that will be time-barred is one where all potential plaintiffs somehow neglect to bring suit after having

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[11] The Third Circuit itself highlights this tension when it calls "ironic" the fact that the dissent, "although noting what might be viewed as Merck's misrepresentations, would apply the statute of limitations to deprive plaintiffs of the opportunity to prove a viable case against Merck for such misrepresentations." *See* App. 47a n.16. That, of course, proves too much, as it is always true that a limitations bar deprives a plaintiff of the opportunity to prove its claims, regardless of whether the claims have merit.

[12] For example, in cases where there is an insignificant drop in the price of a company's stock, no duty to investigate will arise, and the statute of limitations will not run, because any public disclosure was "immaterial as a matter of law." App. 37a. And where there *is* a significant drop in the price of a company's stock, a securities fraud suit will follow almost inevitably, bringing the plaintiff well within the statute of limitations period even if it could have uncovered facts sufficient to state a claim years earlier.

specific evidence of the elements of their claims for more than two years. Such a result misses the point of inquiry notice, whose purpose is not to punish neglectfulness, but to encourage affirmative diligence in ferreting out potential fraud. *See, e.g.*, *Jensen*, 841 F.2d at 607 ("The requirement of diligent inquiry imposes an affirmative duty upon the potential plaintiff."); *Brumbaugh*, 985 F.2d at 163 ("Faced with numerous warnings of an investment's potential risk, the investor cannot simply wait to see if those risks materialize before filing suit.").

II. This Case Presents an Issue of National Importance.

As this Court has repeatedly recognized, the fair and effective operation of federal securities laws is of critical national importance. *See, e.g.*, *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 128 S. Ct. 761, 770 (2008) ("[A] dynamic, free economy presupposes a high degree of integrity in all of its parts, an integrity that must be underwritten by rules enforceable in fair, independent, accessible courts."); *Dabit*, 547 U.S. at 78 ("The magnitude of the federal interest in protecting the integrity and efficient operation of the market for nationally traded securities cannot be overstated.").

Recognizing the central importance of the securities laws, this Court established in *Lampf* a nationwide, uniform statute of limitations for securities fraud claims. As members of this Court observed, this holding was required both by principles of statutory interpretation and by the twin goals of predictability and judicial economy. *See Lampf*, 501 U.S. at 369 (O'Connor, J., dissenting) ("[P]redictability and

judicial economy counsel the adoption of a uniform federal statute of limitations for actions brought under 10(b) and Rule 10b-5"); *id.* at 374 (Kennedy, J., dissenting) ("[A] uniform federal statute of limitations is appropriate for private actions brought under 10(b)."). Congress confirmed the importance of such uniformity when it codified the holding of *Lampf* shortly thereafter. *See* 28 U.S.C. § 1658(b); *see also Tellabs*, 127 S. Ct. at 2509 (observing Congress's desire for "greater uniformity" in the area of federal securities fraud litigation); *Dabit*, 547 U.S. at 86 (noting a "congressional preference for national standards for securities class action lawsuits" (internal quotation marks omitted)).

Uniformity is absent, however, when the timeliness of plaintiffs' claims depends on the forum in which they are brought. Nor is predictability served when some courts commence the statute of limitations clock upon "storm warnings" of fraud while others forestall the statutory clock until a plaintiff has evidence supporting the elements of its claim without the benefit of any investigation.

The result of these divergent standards is confusion for plaintiffs and defendants alike. Under the current standards employed by the Courts of Appeals, defendants can never be sure when the risk of litigation has passed, and plaintiffs have starkly inconsistent directives from the courts as to their duty to investigate potential claims. Forced to keep an eye on the ever-growing number of inquiry notice standards, lower courts will likewise suffer from this confusion.

These inconsistent standards, and particularly the very lenient standard recently adopted by the Third and Ninth Circuits, also contribute to the increasing cost of litigating securities fraud claims. *See Dabit*, 547 U.S. at 81 (noting Congress's observation that securities fraud class actions were "being used to injure the entire U.S. economy" (internal quotation marks omitted)); *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 739 (1975) ("There has been widespread recognition that litigation under Rule 10b-5 presents a danger of vexatiousness different in degree and in kind from that which accompanies litigation in general.").

There is little sense in allowing the circuits to continue to splinter on an issue that is fundamental to the federal securities laws governing our nation's public companies. This Court should grant review to set a national standard and affirm the promise of *Lampf*.

III. This Case is an Optimal Vehicle for Considering the Question Presented.

As discussed above, the question presented here is also raised by another petition for *certiorari* currently pending before the Court. *See Trainer Wortham & Co. v. Betz*, No. 07-1489 (May 27, 2008); *see supra* p. 4. Because the present case is the superior vehicle for considering when the statute of limitations begins to run under an inquiry notice standard, the Court should grant *certiorari* in this case.

First, this case is the better vehicle because it involves a pure question of law. The Third Circuit reviewed the District Court's dismissal under Rule

12(b)(6), accepting the Complaint's factual allegations as true for the purposes of its decision. *See* App. 20a-21a. The Third Circuit thus rested its decision on a straightforward interpretation of the law, which, as demonstrated above, squarely conflicts with the holdings of other Courts of Appeals on the single issue presented by this petition. *See supra* pp. 18-25. Review of the Third Circuit decision would enable this Court to resolve this division.

Second, this petition involves an archetypal securities fraud case: a large, multi-district class action brought against a defendant-corporation based on alleged misrepresentations to the investing public. In such cases, clarification of the correct legal standard is particularly important because the statute of limitations is often raised early in the litigation pursuant to Rule 12(b)(6), with courts taking judicial notice of publicly available information (for example, in this case, the FDA Warning Letter). Moreover, it is precisely these cases where uncertainty imposes the greatest cost on defendants, as even unmeritorious claims may extract "in terrorem" settlements given the pressure exerted by an enormous number of aggregated claims. *See Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347 (2005).

The *Betz* petition, in contrast, does not raise the question presented as clearly. Unlike this case, *Betz* was decided at the summary judgment stage and thus involves disputed issues of fact. *See Betz*, 519 F.3d at 879. Moreover, the *Betz* petition is complicated by the reasonableness of the plaintiff's investigation, the second question presented by the *Betz* petition. Here, because respondents do not allege that they conducted any investigation, this Court need

not sit as a factfinder and weigh the "reasonableness" of a plaintiff's actions, but instead can decide the legal effect of a plaintiff's failure to perform any investigation at all. Finally, *Betz*, where the plaintiff had actual notice of the alleged misrepresentation, involves an uncommon factual scenario. *See id.* at 872. Rarely does such definitive proof of a misrepresentation appear in a case involving inquiry notice.

Petitioners thus respectfully request that the Court grant *certiorari* in the present case. Petitioners request at a minimum that the Court, as it did in *Betz*, invite the Solicitor General to express the views of the United States on the petition.

CONCLUSION

For the reasons stated above, the petition for a writ of *certiorari* should be granted.

January 15, 2009

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APPENDIX

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 07-2431, 07-2432

IN RE: MERCK & CO., INC. SECURITIES,
DERIVATIVE & "ERISA" LITIGATION
(MDL No. 1658)

CONSOLIDATED SECURITIES LITIGATION

Richard Reynolds, Steven LeVan, Jerome Haber and The Public Employees' Retirement System of Mississippi, the Court-Appointed Lead Plaintiffs and Plaintiffs Union Asset Management Holding AG, Loren Arnoff, Robert Edwin Burns, Jan Charles Finance S.A., Martin Mason, Frank H. Saccone, Charlotte Savarese, Joe Savarese, Joseph Goldman, Sherrie B. Knuth, Joseph S. Fisher, M.D., Naomi Raphael, Rhoda Kanter, Park East, Inc. and Marc Nathanson, on behalf of themselves and the proposed class of purchasers of Merck securities during the period between May 21, 1999 and October 29, 2004,

Appellants

On Appeal from the United States District Court
for the District of New Jersey
(D.C. Nos. 05-cv-01151, 05-cv-02367)
District Judge: Honorable Stanley R. Chesler

Argued June 24, 2008

Before: SLOVITER, BARRY, and, ROTH
Circuit Judges

(Filed September 9, 2008)

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OPINION OF THE COURT

SLOVITER, Circuit Judge.

Appellants, purchasers of Merck & Co., Inc. stock, filed the first of several class action securities fraud complaints on November 6, 2003, alleging that the company and certain of its officers and directors (collectively, "Merck") misrepresented the safety profile and commercial viability of Vioxx, a pain reliever that was withdrawn from the market in September 2004 due to safety concerns. The District Court granted Merck's motion to dismiss the complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure, holding that Appellants were put on inquiry notice of the alleged fraud more than two years before they filed suit, and thus their claims were barred by the statute of limitations. Appellants argue that the District Court erred in finding as a matter of law that there was sufficient public information prior to November 6, 2001 to trigger Appellants' duty to investigate the alleged fraud. Because the District Court dismissed on the basis of the complaint, we must accept its allegations as true.[1]

[1] The District Court took judicial notice of the various public documents submitted to it in connection with the motion to dismiss. Appellants do not challenge this decision on appeal and we see no reason to disturb it. "The inquiry notice analysis is an objective one. Whether appellants read the [documents] or were aware of them is immaterial. They serve only to indicate what was in the public realm at the time, not whether the contents of those [documents] were in fact true." Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt., L.P., 435 F.3d 396, 401 n.15 (3d Cir. 2006).

I.

Factual Background

In May 1999, the Food and Drug Administration ("FDA") approved Vioxx, a new drug introduced by the pharmaceutical company Merck. Vioxx is the brand name of rofecoxib, a nonsteroidal anti-inflammatory drug ("NSAID") used in the treatment of arthritis and other acute pain. Most NSAIDs, such as aspirin, ibuprofen, and naproxen, function by inhibiting two enzymes: cyclooxygenase-1 ("COX-1"), which is associated with the maintenance of gastrointestinal ("GI") mucus and platelet aggregation, and cyclooxygenase-2 ("COX-2"), which is associated with the response to pain and inflammation. The inhibition of COX-1 leads to harmful GI side effects. Because Vioxx was designed to suppress COX-2 without affecting COX-1, Merck marketed Vioxx as possessing the beneficial effects of traditional NSAIDs but without the harmful GI side effects associated with those drugs. The market viewed Vioxx as a potential "blockbuster" drug for the company, App. at 469, and as its "savior," App. at 494. Merck repeatedly touted the safety profile, sales, and commercial prospects of the drug in press releases, public statements, and Securities and Exchange Commission ("SEC") filings throughout the class period.

A. Pre-FDA Approval and the VIGOR Study (1996 - March 2000)

Prior to the FDA's approval of Vioxx, officials at Merck were concerned that Vioxx could cause harmful cardiovascular ("CV") events, such as heart

attacks. Internal emails from 1996 and 1997 demonstrate that Merck employees were aware that there was "a substantial chance" and a "possibility" of CV events that could "kill [the] drug." App. at 496. In 1998, an unpublished internal Merck clinical trial entitled Study 090 revealed that Vioxx caused a greater incidence of CV events than a placebo or a different arthritis drug.[2]

In January 1999, Merck commenced the VIOXX Gastrointestinal Outcomes Research ("VIGOR") study, which compared Vioxx to naproxen, the active ingredient in brand-name pain relievers such as Aleve and Naprosyn.[3] Although the study showed that Vioxx had a GI safety profile superior to that of naproxen, it also showed that Vioxx users had a higher incidence of CV events than naproxen users. In a March 9, 2000 email, defendant Edward Scolnick, the President of Merck Research Laboratories, acknowledged the existence of CV events, commenting, "it is a shame but it is a low incidence and it is mechanism based as we worried it was." App. at 512.

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[2] The sources upon which Appellants rely in making these allegations were first made public in November 2004, approximately a year after Appellants filed their initial complaint. See Anna Wilde Mathews & Barbara Martinez, Warning Signs: E-Mails Suggest Merck Knew Vioxx's Dangers at Early Stage, Wall St. J., Nov. 1, 2004, at A1; 60 Minutes (CBS television broadcast Nov. 14, 2001) (transcript available on LexisNexis).

[3] See ALEVE FAQs, http://www.aleve.com/faqs.html#g21 (last visited July 25, 2008); Roche Pharmaceuticals in the U.S., Our Products, Naprosyn, http://www.rocheusa.com/products/naprosyn/ (last visited July 25, 2008).

Merck did not attempt to conceal the results of the VIGOR study. It made them public in a press release on March 27, 2000, that emphasized Vioxx's superior GI safety profile but also noted the incidence of CV events. Merck stated:

> [S]ignificantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation. This effect on these events had not been observed previously in any clinical studies for naproxen. Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects.

App. at 765. The press release also stated that "[a]n extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with Vioxx, showed no indication of a difference in the incidence of thromboembolic events between Vioxx, placebo and comparator NSAIDs." App. at 766.

The VIGOR study results were widely reported in the press, medical journals, and securities analyst reports. Market analysts and members of the press immediately understood that CV events could be a side effect of Vioxx. Nonetheless, many observers also took notice of Merck's hypothesis that naproxen lowered CV events (the "naproxen hypothesis"). The naproxen hypothesis attributed the results of the VIGOR study to the beneficial effects of naproxen's blocking of platelet aggregation rather than to the harmful effects of Vioxx in causing thromboembolic

events. The issue whether naproxen lowered the heart attack risk or Vioxx caused it was thus presented. While many analysts noted that the naproxen hypothesis was unproven, some also concluded that it was the most likely explanation for the increased CV events observed in the VIGOR study.

One representative article distributed by Reuters on April 27, 2000, quoted a Merck spokesman who acknowledged the "statistically significant" finding that patients of Vioxx had a higher rate of CV events, but suggested that this might be explained by a beneficial effect of naproxen. App. at 2287. In that same article, however, a spokesperson for the manufacturer of Naprosyn explained that the company had no knowledge that naproxen prevented heart attacks or strokes; similarly, an analyst for ABN Amro suggested that he was skeptical of Merck's explanation.

B. FDA AAC Hearing (February 8, 2001)

On February 8, 2001, the FDA's Arthritis Advisory Committee ("AAC") held a public hearing to consider Merck's request to include the positive GI results from the VIGOR study in its Vioxx labeling. Six days before that hearing, J.P. Morgan issued a research report summing up the state of knowledge about Vioxx after the VIGOR study. The report stated that the basic idea behind the naproxen hypothesis was "poorly proven," and that there was "no way to retrospectively slice the data to prove the NSAID benefit vs. Vioxx risk argument," although one existing theory "might support a 'Vioxx risk' hypothesis." App. at 2547. J.P. Morgan warned,

"[t]his is the type of clinical 'signal' that was ignored, and later haunted the FDA in recent drug recalls like Warner Lambert's Rezulin and Glaxo's Lotronex." App. at 2547.

During the AAC hearing, defendant Alise Reicin, Executive Director of Clinical Research at Merck Research Laboratories, explained to the panel, "when you review the results of VIGOR in isolation you don't know whether the imbalance of cardiovascular events was caused by a decrease in events on a platelet-inhibiting NSAID, naproxen, or an increase in events on a COX-2 selective inhibitor," i.e., Vioxx. App. at 995. She then suggested that naproxen was likely responsible for the difference in CV events observed in users of the two drugs. At the public portion of the hearing, the panel subsequently discussed whether to call for the inclusion of a warning in the Vioxx labeling stating that it was "uncertain" whether the CV events noticed in VIGOR were "due to beneficial cardioprotective effects of naproxen or prothrombotic effects of [Vioxx], and leave it at that, that basically we don't know the reason." App. at 1143.

Nonetheless, some press accounts reported that certain AAC panel members asserted that "[d]ifferences in cardiac risk between Vioxx and naproxen appeared to result from a beneficial effect of naproxen, not a danger from Vioxx," App. at 2311, and that there was "some reassurance that what we see, in effect, is a protective effect of naproxen," App. at 2306. In subsequent coverage, many securities analysts reported that the hearing had benefited Merck and they continued to project substantial future revenues for Vioxx. However, at least one

investment firm issued a report stating, "our skepticism relating to naproxen having a cardioprotective effect is reinforced" by the AAC hearing. App. at 2703.

C. First Vioxx Product Liability Lawsuit (May 2001)

In May 2001, a product liability lawsuit was filed jointly against Merck and the makers of Celebrex, a rival COX-2 selective inhibitor. The complaint alleged that the pharmaceutical companies "have consistently marketed Vioxx and Celebrex as highly effective pain relief drugs for patients suffering from osteoarthritis," despite the fact that "Merck's own research" demonstrated that "users of Vioxx were four times as likely to suffer heart attacks as compared to other less expensive medications, or combinations thereof." App. at 1748. The plaintiffs sought "emergency notice to class members and revised patient warnings, in the form of additional medical labeling which is presently being considered by the FDA . . . ." App. at 1748.

D. JAMA Article (August 22, 2001)

On August 22, 2001, the Journal of the American Medical Association ("JAMA") reported the results of a study of Vioxx and Celebrex clinical trials. The JAMA article asserted that available data raised a "cautionary flag" about the risk of CV events associated with COX-2 inhibitors. App. at 748. It also stated that "[c]urrent data would suggest that use of selective COX-2 inhibitors might lead to increased cardiovascular events." App. at 752. The day before that article was published, Bloomberg News reported

the statement of a Merck scientist that "[w]e already have additional data beyond what they cite, and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo." App. at 539. The JAMA article garnered extensive coverage. Some securities analysts responding to the article on the date of its publication referred to the basic content of the article as "not new news," App. at 2749, and noted that the FDA "debated many of the same issues in February of this year," at the AAC panel hearing. App. at 2751.

The day after the JAMA article's publication, Merck issued a press release stating that it "stands behind the overall and cardiovascular safety profile . . . of VIOXX." App. at 540. Merck also sent "'Dear Doctor' letters to physicians throughout the country disparaging the article as 'not based on any new clinical study' and assuring the physicians that Merck 'stands behind the overall and cardiovascular safety profile' of VIOXX.'" App. at 540.

E. FDA Warning Letter (September 21, 2001)

On September 21, 2001, the FDA posted on its website a warning letter that its Division of Drug Marketing, Advertising, and Communications ("DDMAC") had sent to Merck four days earlier regarding its marketing and promotion of Vioxx. In the letter, the DDMAC stated that Merck's "promotional activities and materials" for the marketing of Vioxx were "false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and

applicable regulations." App. at 713. The letter explained:

> You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the [VIGOR] study, and thus, misrepresents the safety profile for Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).
>
> Although the exact reason for the increased rate of MIs observed in the Vioxx treatment group is unknown, your promotional campaign selectively presents the following hypothetical explanation for the observed increase in MIs. You assert that Vioxx does not increase the risk of MIs and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties.

App. at 713. The letter also directed Merck to issue "Dear Healthcare provider" letters "to correct false or misleading impressions and information." App. at 719.

The FDA warning letter received widespread coverage by the media and securities analysts. Although many media reports focused on the mere fact of the warning letter,[4] securities analysts tended to emphasize the impact the warning letter would likely have on the prospective Vioxx labeling changes (which were not forthcoming until April 2002),[5]

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[4] A few representative examples follow: Reuters -- "U.S. regulators have charged . . . Merck . . . with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks." App. at 2353. Associated Press -- "Merck has argued that [the VIGOR study results make] Vioxx falsely look[] risky because naproxen thins the blood . . . and thus protect[s] against heart attacks. . . . 'In fact, the situation is not at all clear,' [according to] the FDA . . . ." App. at 2360. USA Today -- "Merck's marketing efforts, aimed mainly at doctors, have minimized Vioxx's known and potential cardiovascular risks, the FDA wrote in an eight-page 'warning letter' . . . . So far this year, the FDA has sent drug companies fewer than a dozen warning letters, which the agency reserves for activities that raise significant public health concerns." App. at 2355. Wall Street Journal -- "Federal regulators warned Merck & Co. for improper marketing of its blockbuster arthritis drug Vioxx, saying the company had misrepresented the drug's safety profile and minimized its potential risks. . . . While the FDA sends out dozens of routine citations annually, it issues only a handful of these more-serious warning letters each year." App. at 2361.

[5] For example, a report issued by Lehman Brothers stated: "We do not believe this letter will be predictive of the FDA's actions on the pending Vioxx label change. . . . Warning letters of this nature are certainly not unusual and in fact almost a staple of the pharmaceutical industry today. . . . As pointed out in the FDA warning letter, DDMAC does not dispute Merck's claims." App. at 2765-66.

Merck's ongoing promotional efforts,[6] and Merck's position in the market.[7] A report issued by UBS Warburg explained, "[t]he FDA pointed out that there is no definitive study proving or disproving either conclusion [regarding the higher incidence of CV events associated with Vioxx in the VIGOR study]. . . . The FDA's position appears similar to our own, which is that the data available to date are simply not definitive." App. at 2768. Nonetheless, securities analysts were of one voice in their projections for Merck and Vioxx; analysts from CIBC World Markets, Credit Suisse First Boston ("CSFB"), Dain Rauscher, Lehman Brothers, UBS Warburg, SG Cowen, and Morgan Stanley all maintained their ratings for Merck stock at "buy" or "hold" and/or continued to project increased future revenues for Vioxx.

In the five days between September 20, 2001 and September 25, 2001, Merck's stock price declined

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[6] One report issued by Merrill Lynch stated: "The FDA issued a warning letter to Merck . . . [and] is looking for Merck to cease all violative promotional activities . . . . We do not see how this issue can be helpful to Merck in promoting Vioxx." App. at 2752.

[7] A Dain Rauscher report focused on Vioxx's position in the actual marketplace, i.e., the doctor's office: "We believe th[e FDA warning letter] is unlikely to significantly alter physicians' prescribing practices [because it] is likely that these issues are already common knowledge in the medical community . . . ." App. at 2762. Meanwhile, a CIBC World Markets report considered how the warning letter might impact Merck's stock price: "The FDA warning letter as well as a recent JAMA article raising concerns of cardiovascular risk will continue to pressure the stock, now trading close to its 52-week low." App. at 2755.

by $4.16, or 6.6%, closing at $59.11 on September 25. Reuters reported this drop on September 25, explaining that "[s]hares of Merck & Co. fell . . . after U.S. regulators accused the firm of making unsubstantiated claims about its hot-selling arthritis drug Vioxx and downplaying a possible risk of heart attack from taking the medicine." App. at 2357. By October 1, 2001, however, Merck's stock price had rebounded to $64.66, $1.39 higher than its closing price before the warning letter was made public just over a week earlier.

F. Additional Vioxx Lawsuits (September 27, 2001)

A consumer fraud lawsuit was filed against Merck on behalf of Vioxx users on September 27, 2001. A second product liability lawsuit and a personal injury lawsuit followed shortly thereafter. In articulating their allegations of fraud and misrepresentations by Merck to consumers and Vioxx users, the consumer fraud and product liability suits relied in large part on the JAMA article, the FDA warning letter, and various media reports concerning Vioxx.

G. New York Times Article (October 9, 2001)

On October 9, 2001, the New York Times published an article about COX-2 inhibitors entitled "The Doctor's World; For Pain Reliever, Questions of Risk Remain Unresolved." App. at 653. The article reported on "troubling questions about whether Vioxx may have an unexpected side effect -- a very slight increase in the risk of heart attack." App. at

653. However, the article explained that "[t]he risk is hypothesized, not proved," and that "leading arthritis specialists . . . say that they are not concerned and that they prescribe the drugs for patients who may have heart disease." App. at 653. The article noted that "[a]t issue is the subtle question of what counts as evidence," App. at 653, explaining that the risk that COX-2 inhibitors cause blood-clotting was originally posed as a theory a few years earlier by a scientist from the University of Pennsylvania.

The article addressed defendant Scolnick's statements at length. According to the article, Scolnick said that Merck "look[ed] specifically for excess heart attacks and strokes in" the VIGOR study and found a higher incidence in the patients taking Vioxx. App. at 654. "'There are two possible interpretations,' Dr. Scolnick said. 'Naproxen lowers the heart attack rate, or Vioxx raises it.'" App. at 654. The article went on, "while [Merck] announced the heart attack findings to doctors and the public, it looked back at its data from studies using different drugs or dummy pills in comparison to Vioxx. It found no evidence that Vioxx increased the risk of heart attacks, Dr. Scolnick said." App. at 654. "He said that the company decided that 'the likeliest interpretation of the data is that naproxen lowered . . . the thrombotic event rate' . . . . He added that without the theoretical question raised by [the University of Pennsylvania scientist], 'no one would have a question remaining in their mind that their [sic] might be an additional interpretation.'" App. at 654. The article reported Scolnick as conceding that "none of the findings to date are enough to prove that the issue is fully resolved. That lack of proof is why

the F.D.A. demanded that Merck explain both sides of the hypothesis, telling doctors and patients that it is not known whether naproxen protects against heart attacks or Vioxx makes them more likely." App. at 654.

There was no significant movement in Merck's stock price following the publication of the New York Times article.

H. Vioxx's Labeling Modified to Include CV Risks (April 2002)

Merck was not required to include the risk of CV events in its labeling until April 2002. The labeling ultimately incorporating that information explained the VIGOR study results and stated, "the risk of developing a serious cardiovascular thrombotic event was significantly higher in patients treated with VIOXX . . . as compared to patients treated with naproxen . . . . The significance of the cardiovascular findings . . . is unknown." App. at 553. This language was incorporated into the "precautions" section of the Vioxx labeling, rather than the "warnings" section. In a conference call discussing the labeling changes, a Merck spokesperson reiterated the company's "belief that the effect seen in VIGOR were [sic] the results of the anti-platelet effect of naproxen. . . . So, I think that's a position Merck has always had and now its [sic] quite clearly laid out in the labeling." App. at 559.

I. Falling Vioxx Sales and the Harvard Study (October 2003)

On October 22, 2003, Reuters published an article entitled "Merck to Cut 4,400 Jobs, posts Flat Earnings," in which it reported that Merck was "hurt by falling sales of arthritis medicine VIOXX and a paucity of profitable new drugs. . . . The arthritis drug is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks . . . ." App. at 570. That day, Merck's stock price dropped from $48.91 to $45.72, down 6.5%.

On October 30, 2003, the Wall Street Journal published an article entitled "VIOXX Study Sees Heart-Attack Risk," which addressed a recent study by the Harvard-affiliated Brigham and Women's Hospital in Boston that found an increased risk of heart attack in patients taking Vioxx compared with patients taking Celebrex and placebo (the "Harvard study"). App. at 571. According to the article, "[i]n the first 30 days, the researchers found, VIOXX was linked to a 39% increased heart-attack risk compared with Celebrex. Between 30 and 90 days, that increased relative risk was 37%." App. at 571. A researcher stated that this was "the best study to date" and that it "greatly substantiates our concerns about the cardiac side effects" of Vioxx. App. at 571.

Merck's stock price dropped below the S&P 500 Index during this time, and did not rise above that index during the remainder of the class period.

J. Merck Withdraws Vioxx From the Market (September 2004)

On September 30, 2004, Merck announced that it was withdrawing Vioxx from the market based on a new study showing an "increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy." App. at 584. Merck's stock price dropped more than $12 per share that day, to close at $33.00, down 27% from the previous day's close. Securities analysts expressed their surprise at the suddenness of Merck's action.

On November 1, 2004, the Wall Street Journal reported, "internal Merck e-mails and marketing materials as well as interviews with outside scientists show that the company fought forcefully for years to keep safety concerns from destroying the drug's commercial prospects." App. at 589. Merck's stock price dropped another 9.7% based on this news. The news, which was first published nearly a year after Appellants filed their complaint, prompted one securities analyst to remark, "new information indicates to us that the situation might not be as innocent as we thought. . . . We recommend that investors sell Merck shares." App. at 594.

II.

Procedural History

The first class action securities complaint initiating this lawsuit was filed on November 6, 2003, just weeks after the media reported the results of the Harvard study and declining Vioxx sales. After numerous nationwide class actions were

consolidated, Appellants filed a fourth amended consolidated class action complaint. The complaint alleged that "Defendants' statements and omissions during the Class Period materially misrepresented the safety and commercial viability of VIOXX," App. at 489, in violation of sections 11, 12(a)(2), and 15 of the Securities Act of 1933, sections 10(b), 20(a), and 20A of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder.

Merck moved to dismiss Appellants' claims on the grounds that they were time-barred and that Appellants had failed to state a claim. The District Court granted that motion on the basis that the claims were time-barred. In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig., 483 F. Supp. 2d 407, 425 (D.N.J. 2007).[8] Appellants timely filed a notice of appeal.

III.

Jurisdiction and Standard of Review

The District Court had jurisdiction over this action pursuant to section 22 of the Securities Act, 15 U.S.C. § 77v; section 27 of the Securities Exchange Act, 15 U.S.C. § 78aa; and 28 U.S.C. § 1331. We have jurisdiction pursuant to 28 U.S.C. § 1291. We exercise plenary review over the District Court's

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[8] The District Court did not address Merck's argument that the allegations contained in the fourth amended consolidated class action complaint failed to satisfy the heightened standards of the Private Securities Litigation Reform Act of 1995 for pleading scienter, and we do not express any opinion on this issue.

dismissal of Appellants' claims for failure to comply with the statute of limitations. DeBenedictis v. Merrill Lynch & Co., Inc., 492 F.3d 209, 215 (3d Cir. 2007). Because the District Court granted Merck's motion to dismiss, "[w]e must 'accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party.'" Id. (quoting Rocks v. City of Philadelphia, 868 F.2d 644, 645 (3d Cir. 1989)). The dismissal must be upheld only "'if it appears to a certainty that no relief could be granted under any set of facts which could be proved.'" Id. (quoting D.P. Enters., Inc. v. Bucks County Cmty. Coll., 725 F.2d 943, 944 (3d Cir. 1984)).

IV.

Discussion

The relevant statutes each contain their own statute of limitations. A complaint alleging "fraud, deceit, manipulation, or contrivance" under the Securities Exchange Act "may be brought not later than the earlier of . . . 2 years after the discovery of the facts constituting the violation; or . . . 5 years after such violation." 28 U.S.C. § 1658(b). Claims under the Securities Act are subject to a shorter, one-year limitation period from the time of discovery, but in no event may be filed later than three years after the public offering or sale of the security. 15 U.S.C. § 77m. Thus, if Appellants knew of the basis for their claims prior to November 6, 2001, two years before the first securities complaint was filed, all of their claims are barred by the statute of limitations. See DeBenedictis, 492 F.3d at 216.

"Whether the plaintiffs, in the exercise of reasonable diligence, should have known of the basis for their claims depends on whether they had 'sufficient information of possible wrongdoing to place them on 'inquiry notice' or to excite 'storm warnings' of culpable activity.'" Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt., L.P., 435 F.3d 396, 400 (3d Cir. 2006) (quoting In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1325 (3d Cir. 2002)). This is an objective question: thus, an investor is not on inquiry notice until a "'reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning.'" In re NAHC, 306 F.3d at 1325 (quoting Mathews v. Kidder, Peabody & Co., 260 F.3d 239, 252 (3d Cir. 2001)).

"If the existence of storm warnings is adequately established the burden shifts to the plaintiffs to show that they exercised reasonable due diligence and yet were unable to discover their injuries." DeBenedictis, 492 F.3d at 216 (citations, alterations, and internal quotation marks omitted). Here, the District Court held that Appellants were on inquiry notice of their claims no later than October 9, 2001, the date the New York Times published the article reporting that defendant Scolnick "acknowledged that Merck knew that the cardioprotective effect of naproxen was not proven and, further, that Merck admitted that VIOXX may raise the risk of heart attack or other thrombotic event." In re Merck, 483 F. Supp. 2d at 419. The Court also noted what it characterized as the "overwhelming collection of information signaling deceit by Merck with respect to the safety of VIOXX [that] had accumulated in the public realm" by that

date, in particular, the FDA warning letter. Id. In concluding that sufficient storm warnings of fraud existed more than two years prior to the filing of Appellants' complaint, the District Court observed that Appellants' "position that their claims did not accrue until the existence of fraud was a probability, as opposed to a possibility ... is simply not supported by Third Circuit law." Id. at 422. Finally, noting that Appellants had "not argued that they conducted a diligent investigation, and nothing in the Complaint demonstrates that they were unable to uncover pertinent information during the limitations period," the Court concluded that Appellants' claims were time-barred and granted Merck's motion to dismiss. Id. at 424.

A. Principles of Inquiry Notice

Before reviewing the District Court's decision, we must address an ambiguity in our inquiry notice jurisprudence. Appellants contend that the statute of limitations does not begin to run until there is sufficient evidence of probable, rather than possible, wrongdoing by the defendants. Predictably, Merck supports the latter standard, arguing that inquiry notice may be triggered by evidence of possible wrongdoing. Both formulations find support in this court's precedents. Compare DeBenedictis, 492 F.3d at 216 (Inquiry notice may be established by proof of "'financial, legal, or other data that would alert a reasonable person to the probability that misleading statements or significant omissions had been made.'") (quoting In re NAHC, 306 F.3d at 1326-27 n.5) (emphasis added), with Benak, 435 F.3d at 400 ("'Whether the plaintiffs ... should have known of the basis for their claims depends on whether they

had "sufficient information of possible wrongdoing to place them on 'inquiry notice' . . . ."") (quoting In re NAHC, 306 F.3d at 1325) (emphasis added). We therefore take this opportunity to clarify the standard for inquiry notice in this circuit.

Our first comprehensive discussion of the appropriate standard for inquiry notice took place in the context of a claim filed pursuant to the Racketeer Influenced and Corrupt Organizations Act ("RICO").[9] See Mathews, 260 F.3d at 241. In Mathews, investors in low-risk securities sued their broker after the securities had lost more than half their value, alleging that the broker misled them about the nature of the funds and charged excessive fees and commissions. We affirmed the district court's grant of summary judgment for the broker because the complaint was time-barred. Id. at 244. In analyzing whether plaintiffs' suit was filed before RICO's statute of limitations had run, we applied a two-pronged test derived from the inquiry notice standard other courts had applied in the context of securities fraud claims. Id. at 251-52.

First, we noted the requirement to make an objective inquiry into whether the defendant had met its burden "to show the existence of 'storm warnings.'" Id. at 252. We explained that storm warnings "may take numerous forms," such as "'any financial, legal or other data that would alert a

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[9] Quoting extensively from Mathews, we recently reiterated the inquiry notice standard for RICO claims in Cetel v. Kirwan Financial Group, Inc., 460 F.3d 494, 506-07 (3d Cir. 2006).

reasonable person to the probability that misleading statements or significant omissions had been made.'" Id. (quoting unpublished district court opinion).[10] Second, we described an inquiry, "both subjective and objective," into whether the plaintiffs had met their burden "to show that they exercised reasonable due diligence and yet were unable to discover their injuries." Id. We then noted our agreement with the Court of Appeals for the Seventh Circuit that courts should be "mindful of the dangers in adopting too broad an interpretation of inquiry notice." Id. at 253 (citing Law v. Medco Research, Inc. ("Medco II"), 113 F.3d 781, 786 (7th Cir. 1997); Fujisawa Pharm. Co. v. Kapoor, 115 F.3d 1332, 1335 (7th Cir. 1997)).

A year later, we applied this standard to claims pleaded under the federal securities laws. See In re NAHC, 306 F.3d at 1318. The shareholders' claims in that case arose from a health care provider's collapse after the federal government enacted regulations that negatively impacted the provider's long-term care services business. Id. at 1318-21. In formally adopting the inquiry notice standard for securities claims, we stated that "[w]hether the plaintiffs, in the exercise of reasonable diligence, should have known of the basis for their claims depends on

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[10] Immediately before using this language regarding a "probability" of fraud, we noted without criticism that the district court had also framed the first prong of the inquiry notice standard as "'whether the plaintiffs knew or should have known of the possibility of fraud ("storm warnings") . . . .'" Mathews, 260 F.3d at 251-52 (quoting unpublished district court opinion). Thus, there is no basis to conclude that we rejected the notion of a possibility standard at that time.

whether they had 'sufficient information of possible wrongdoing to place them on "inquiry notice" or to excite "storm warnings" of culpable activity.'"[11] Id. at 1325 (quoting Gruber v. Price Waterhouse, 697 F. Supp. 859, 864 (E.D. Pa. 1988)). We explained that "[p]laintiffs need not know all of the details or 'narrow aspects' of the alleged fraud to trigger the limitations period; instead, the period begins to run from 'the time at which plaintiff should have discovered the general fraudulent scheme.'" Id. at 1326 (quoting In re Prudential Ins. Co. Sales Practices Litig., 975 F. Supp. 584, 599 (D.N.J. 1997)).

In affirming the district court's dismissal of the plaintiffs' claim arising from the impact of the federal regulations on the defendants' long-term care services business, we held that a series of disclosures, which accompanied a drastic decline in the company's stock price, id. at 1319, and culminated with the defendants' announcement that they were writing off goodwill and selling their business for nominal consideration, put the plaintiffs on inquiry notice that previous valuations of goodwill had been inflated, id. at 1326-27. This holding was bolstered by the plaintiffs' admission that the market had written off that business even before the defendants' announcement. Id. at 1327.

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[11] In a footnote of the same opinion, however, we stated that inquiry notice could be established on the basis of "'data that would alert a reasonable person to the probability that misleading statements or significant omissions had been made.'" See In re NAHC, 306 F.3d at 1325-26 n.5 (quoting Mathews, 260 F.3d at 252).

More recently, in 2006, we considered whether a suit filed by mutual fund investors against fund advisors who had invested heavily in Enron was barred by the statute of limitations. Benak, 435 F.3d at 397. In our decision, we dispensed with the probability language altogether, instead holding that storm warnings could be triggered by "'sufficient information of possible wrongdoing . . . .'" Id. at 400 (quoting In re NAHC, 306 F.3d at 1325). Applying our inquiry notice standard to the facts of that case, we distinguished mutual fund investors from direct investors on the ground that mutual fund investors rely on an intermediary to learn about the companies in which they have invested. Id. at 401-02. Nonetheless, because the investors in Benak had access to media reports about their fund's large holdings in Enron after that company went bankrupt, we concluded that the plaintiffs were on inquiry notice of the fraud by the time the media reported the bankruptcy. Id. at 402-03.

Finally, in a case decided just last year, we considered investors' claims that Merrill Lynch misled them by failing to disclose that a certain class of mutual fund shares was "never a rational choice of investment for them and that Merrill brokers received larger commissions on sales of such shares." DeBenedictis, 492 F.3d at 210. Merrill argued that news articles, National Association of Securities Dealers ("NASD") press releases, and the mutual funds' registration statements put the class on inquiry notice more than two years before the complaint was filed and that it should therefore be dismissed as time-barred. Id. at 214. After quoting the "probability" language first used by the district

court in Mathews, we addressed each category of storm warnings alleged. We noted that Merrill's registration statements disclosed the fee structure for the different classes of shares, which allowed investors to determine the relative costs and benefits of the different shares, and the different commissions applying to those shares. Id. at 216-17. We further concluded that storm warnings existed because the news reports and press releases identified by the defendants revealed that many brokers had been disciplined by the NASD for recommending the very class of shares that undergirded the plaintiffs' claims. Id. at 217. Accordingly, we concluded that the plaintiffs' claims were time-barred.

As this review of our precedent makes clear, although we have occasionally stated that inquiry notice may be triggered by evidence alerting an investor to the probability of wrongdoing, we have just as often emphasized that inquiry notice may be triggered by sufficient information of possible wrongdoing. This implies that a probability, in the sense of a nearly certain likelihood, of wrongdoing is not necessary to trigger storm warnings in this circuit. Therefore, we reaffirm that "whether the plaintiffs, in the exercise of reasonable diligence, should have known of the basis for their claims depends on whether they had sufficient information of possible wrongdoing to place them on inquiry notice or to excite storm warnings of culpable activity." Benak, 435 F.3d at 400 (citations, alteration, and internal quotation marks omitted). In so holding, we note that the majority of courts of appeals to have addressed the question employ a possibility standard when evaluating the likelihood

of wrongdoing sufficient to constitute storm warnings. See, e.g., GO Computer, Inc. v. Microsoft Corp., 508 F.3d 170, 179 (4th Cir. 2007); Tello v. Dean Witter Reynolds, Inc., 494 F.3d 956, 970 (11th Cir. 2007); Wolinetz v. Berkshire Life Ins. Co., 361 F.3d 44, 48 (1st Cir. 2004); Ritchey v. Horner, 244 F.3d 635, 639 (8th Cir. 2001); Berry v. Valence Tech., Inc., 175 F.3d 699, 705 (9th Cir. 1999); Sterlin v. Biomune Sys., 154 F.3d 1191, 1196 (10th Cir. 1998); LaSalle v. Medco Research, Inc. ("Medco I"), 54 F.3d 443, 444 (7th Cir. 1995); Jensen v. Snellings, 841 F.2d 600, 607 (5th Cir. 1988). But see Newman v. Warnaco Group, Inc., 335 F.3d 187, 193 (2d Cir. 2003) ("The [existence of] fraud must be probable, not merely possible.").

Nonetheless, simply repeating the word "possibility" or "probability" with ever-increasing frequency and intensity (as both parties did in their briefs and at oral argument) is hardly useful. Rather, we review the information set forth by the parties with an eye toward the practical effect of drawing the inquiry notice line at a particular date. In this vein, we have emphasized that "[u]ndergirding the inquiry notice analysis is the assumption that a plaintiff either was or should have been able, in the exercise of reasonable diligence, to file an adequately pled securities fraud complaint as of an earlier date." Benak, 435 F.3d at 401. Similarly, the Court of Appeals for the Seventh Circuit, which has also applied a possibility standard, see Medco I, 54 F.3d at 444, has reasoned that "[t]he facts constituting [inquiry] notice must be sufficiently probative of fraud–sufficiently advanced beyond the stage of a mere suspicion, sufficiently confirmed or

substantiated–not only to incite the victim to investigate but also to enable him to tie up any loose ends and complete the investigation in time to file a timely suit," Fujisawa, 115 F.3d at 1335. In other words, simply stating that a smattering of evidence hinted at the possibility of some type of fraud does not answer the question whether there was "sufficient information of possible wrongdoing . . . to excite storm warnings of culpable activity" under the securities laws. Benak, 435 F.3d at 400 (citations and internal quotation marks omitted) (emphasis added).

This concern is reenforced by the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4(b).[12] Surely, Congress did not envision a statute of limitations that would open the floodgates to a rush of premature securities litigation when its primary foray into this field in recent decades has been to deter poorly pleaded allegations of securities fraud. See DeBenedictis, 492 F.3d at 217-18 (noting that "'the level of particularity in pleading required by the PSLRA is such that inquiry notice can be established only where the triggering data "relates directly to the misrepresentations and omissions" alleged.'") (quoting Lentell v. Merrill Lynch & Co., 396 F.3d 161, 171 (2d Cir. 2005)); cf. Mathews, 260

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[12] The PSLRA requires plaintiffs pleading securities fraud to "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading," 15 U.S.C. § 78u-4(b)(1), and to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," i.e., scienter, id. § 78u-4(b)(2).

F.3d at 253 (expressing concern about "a flood of untimely litigation" were we to "adopt[] too broad an interpretation of inquiry notice").

B. Basis of Appellants' Claims

Appellants argue that the District Court mischaracterized the gravamen of their fraud allegations, thereby undermining the Court's conclusion that Appellants were on inquiry notice of the alleged wrongdoing. We have repeatedly stated that the fundamental concern of our analysis is whether plaintiffs were "'on inquiry notice of the basis for [their] claims'" prior to the relevant date triggering the statute of limitations. Benak, 435 F.3d at 400 (quoting In re NAHC, 306 F.3d at 1325). Therefore, we must carefully scrutinize the District Court's characterization of the basis for Appellants' claims and consider how this characterization affected the Court's inquiry notice analysis.

First, Appellants contend that the Court mischaracterized the basis for their claims by focusing on alleged misrepresentations about Vioxx's safety profile. In concluding that sufficient storm warnings existed to put Appellants on inquiry notice, the District Court considered the "overwhelming collection of information signaling deceit by Merck with respect to the safety of VIOXX [that] had accumulated in the public realm" by October 9, 2001. In re Merck, 483 F. Supp. 2d at 419. Appellants argue that the true nature of their claims is that Vioxx "was so dangerous that it lacked any meaningful commercial prospects, or that [Merck's] representations in this regard were materially false and misleading when made . . . ." Appellant's Br. at

35. The difficulty with this contention is that Merck's representations about Vioxx's commercial viability are not unrelated to the company's representations about the drug's safety profile. If public information undermined Merck's representations about Vioxx's safety, a reasonable investor would also likely see such information as undermining Merck's representations about Vioxx's commercial viability. Indeed, some professional investors connected concerns about the safety of COX-2 inhibitors to their commercial viability.

Nonetheless, the fact that many securities analysts continued to maintain strong growth ratings for Vioxx at the same time that its safety was being questioned is certainly relevant to whether such questions constituted sufficient information of possible wrongdoing to trigger storm warnings. Even though there were analysts who connected Vioxx's safety to its commercial viability, it appears that they were not so worried about Vioxx's safety after the FDA warning letter was made public that they felt it necessary to retract their opinions about Vioxx's future profitability or Merck's market position.[13] In any event, Appellants argue that even

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[13] A September 25, 2001 report by a CSFB analyst illustrates the interrelatedness of the two propositions: "Recent prescription trends have indicated that adverse publicity and cardiovascular concerns have contributed to erosion in Vioxx (as well as Celebrex) market share within the collective COX-2/NSAID market." App. at 2757. On the other hand, the same CSFB report also "project[ed] Vioxx revenues will increase 42% year over year to $3.06 billion for 2001, with growth moderating to the +14% level in 2002 to $3.49 billion. We maintain our Buy rating." App. at 2757.

if their claims are properly characterized as alleging misrepresentations about Vioxx's safety, the District Court misinterpreted their claims in another respect.

Appellants contend that their complaint challenges the veracity of Merck's statements of opinion and belief regarding the naproxen hypothesis whereas the District Court analyzed whether Merck misrepresented the fact that the results of the VIGOR study could support multiple hypotheses (i.e., that naproxen lowers the risk of CV events or that Vioxx raises that risk). Thus, they argue that the District Court mischaracterized their claims by considering whether there were storm warnings that put them on notice of a fraud different from that which they have asserted in their complaint.

We have explained that for "misrepresentations in an opinion" or belief to be actionable, plaintiffs must show that the statement was "'issued without a genuine belief or reasonable basis' . . . ." Herskowitz v. Nutri/System, Inc., 857 F.2d 179, 185 (3d Cir. 1988) (quoting Eisenberg v. Gagnon, 766 F.2d 770, 776 (3d Cir. 1985)); accord Va. Bankshares, Inc. v. Sandberg, 501 U.S. 1083, 1095 (1991) ("A statement of belief may be open to objection . . . as a misstatement of the psychological fact of the speaker's belief in what he says."). Thus, to trigger "storm warnings of culpable activity," Benak, 435 F.3d at 400 (citations and internal quotation marks omitted), in the context of a claim alleging falsely-held opinions or beliefs, investors must have sufficient information to suspect that the defendants engaged in culpable activity, i.e., that they did not hold those opinions or beliefs in earnest. Appellants' theory in the complaint is that Merck's statements

about the validity of the naproxen hypothesis were falsely-held statements of opinion or belief and that there was no information available to investors prior to November 6, 2001 that would have led them to suspect that such statements were not held in earnest. The District Court rejected this argument, concluding that "[i]t is prepost[e]rous for Plaintiffs to argue that because they did not have a 'smoking gun' that demonstrated that Defendants' misrepresentation was even more egregious than the [FDA] Warning Letter charged, they were not on inquiry notice of a general fraudulent scheme regarding the safety of VIOXX." In re Merck, 483 F. Supp. 2d at 422-23. We disagree.

It is true that "[p]laintiffs cannot avoid the time bar simply by claiming they lacked knowledge of the details or narrow aspects of the alleged fraud. Rather, the clock starts when they should have discovered the general fraudulent scheme." Benak, 435 F.3d at 400 (citations and internal quotation marks omitted). The "fraudulent scheme" referred to must be one "in connection with the purchase or sale of any security . . . ." 15 U.S.C. § 78j(b). Appellants have brought a securities fraud action, not a consumer fraud action, against Merck. See Gavin v. AT & T Corp., 464 F.3d 634, 640 (7th Cir. 2006) (recognizing that securities fraud suits and consumer fraud suits are not interchangeable); cf. Marine Bank v. Weaver, 455 U.S. 551, 556 (1982) ("Congress, in enacting the securities laws, did not intend to provide a broad federal remedy for all fraud."). Thus, the fact that the FDA sent a letter to Merck about its possible misrepresentations in connection with its promotion of Vioxx to health care professionals

would not have provided a storm warning unless it put Appellants on inquiry notice of actionable misrepresentations under the securities laws. See DeBenedictis, 492 F.3d at 218 (finding storm warning where disclosure was "directly applicable to the representations or omissions" challenged by plaintiffs). The asserted basis of Appellants' claims is that Merck defrauded investors by proposing and reasserting the naproxen hypothesis at the same time that it knew the hypothesis was false. We must analyze the existence of storm warnings relative to that allegation in order to determine whether Appellants were on inquiry notice of the alleged fraud.

C. Existence of Storm Warnings

Because the District Court believed that "[t]he wrongdoing charged in the [FDA] Warning Letter is . . . the same alleged misconduct on which the securities fraud claims in this case are predicated," the Court asserted that it "might arguably conclude that the FDA Warning Letter alone excited storm warnings sufficient to put Plaintiffs on inquiry notice of their claims against Merck," but it decided that it "need not make that conclusion, because the FDA Warning Letter was not issued in a vacuum of information." In re Merck, 483 F. Supp. 2d at 419. The Court then took notice of the JAMA article, the lawsuits filed against Merck in 2001, and various articles discussing competing explanations for the results of the VIGOR study. Id. at 419-21. The Court reasoned that the New York Times article following the FDA warning letter was especially probative because Scolnick "admitted that Merck recognized the possibility that VIOXX may increase a user's risk

of heart attack. It therefore represents a significant departure from Merck's company line as to the explanation for the VIGOR study results." Id. at 420. The Court then rejected Appellants' argument that positive information issued by Merck during this period dissipated any storm warnings. Id. at 421.

Appellants argue that to the extent the disclosures identified by Merck might be seen as triggering storm warnings, such storm warnings were dissipated by Merck's reassuring statements,[14] and are undermined by the failure of the identified disclosures to have any significant impact on Merck's stock price or the projections of securities analysts covering Merck. Merck argues that stock price movement is irrelevant to the inquiry notice analysis. We cannot agree. Our past inquiry notice decisions have taken into account the market reaction to disclosures that purportedly constitute storm warnings. See, e.g., In re NAHC, 306 F.3d at 1319 (discussing drastic decline in stock price accompanying disclosures in period leading up to date of inquiry notice); cf. Benak, 435 F.3d at 403

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[14] We have recognized that "reassurances can dissipate apparent storm warnings if an investor of ordinary intelligence would reasonably rely on them to allay the investor's concerns." Benak, 435 F.3d at 402 n.16 (citation, alteration, and internal quotation marks omitted). "Whether reassuring statements justify reasonable reliance that apparent storm warnings have dissipated will depend in large part on how significant the company's disclosed problems are, how likely they are of a recurring nature, and how substantial are the 'reassuring' steps announced to avoid their recurrence." DeBenedictis, 492 F.3d at 218 (quoting LC Capital Partners, LP v. Frontier Ins. Group, Inc., 318 F.3d 148, 155 (2d Cir. 2003)).

(noting that Enron's collapse and subsequent bankruptcy triggered inquiry notice); Mathews, 260 F.3d at 254 (explaining that 30% drop in funds' net asset values and 60% decline in distributions triggered inquiry notice). In Mathews, we explained that "in most securities fraud actions, the plaintiffs' [losses] are inextricably intertwined with the defendant's misrepresentations. Discovery of one leads almost immediately to discovery of the other." Mathews, 260 F.3d at 251. Similarly, in the context of materiality, we have stated that in "an efficient market, 'information important to reasonable investors . . . is immediately incorporated into the stock price.'" Oran v. Stafford, 226 F.3d 275, 282 (3d Cir. 2000) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1425 (3d Cir. 1997)). "If the disclosure of certain information has no effect on stock prices, it follows that the information disclosed was immaterial as a matter of law." In re NAHC, 306 F.3d at 1330 (citing In re Burlington Coat Factory, 114 F.3d at 1425).

Because information that is material to reasonable investors is immediately incorporated into the stock price, the effect of a purported storm warning on the market, while insufficient on its own to compel the conclusion that inquiry notice has not been triggered, is, contrary to Merck's position, relevant to our inquiry. See Newman, 335 F.3d at 195 (asserting that the court's "holding is further supported by the fact that [defendant]'s stock price did not have any significant movement following" the identified disclosure); Berry, 175 F.3d at 705 (concluding that the lack of significant stock

movement "bolster[ed]" the conclusion that inquiry notice had not been triggered).

The District Court (and Merck on this appeal) emphasized five classes of information, each of which was disclosed on or before October 9, 2001, which purportedly triggered storm warnings: (1) articles and reports commenting on the hypothetical explanations for the results of the VIGOR study; (2) the JAMA article, which asserted that available data (i.e., VIGOR and a Celebrex study) raised a "cautionary flag" about the risk of CV events in COX-2 inhibitors, App. at 748; (3) the FDA warning letter, which charged Merck with "engag[ing] in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the [VIGOR] study, and thus, misrepresents the safety profile for Vioxx," App. at 713; (4) the consumer fraud, product liability, and personal injury lawsuits filed against Merck throughout 2001; and (5) the New York Times article, in which Scolnick stated there were "two possible interpretations" for the VIGOR results, App. at 654. Because the disclosures in each of these categories ultimately arise from the results of the VIGOR study, we briefly recap the details of the study.

VIGOR compared Vioxx to naproxen in the hopes of establishing that Vioxx had a better GI profile than traditional NSAIDs. Although those hopes were realized, Merck also learned, and subsequently notified the public, that "significantly fewer thromboembolic events were observed in patients taking naproxen" than patients taking Vioxx. App. at 765. Merck suggested that naproxen's

effect on platelet aggregation was responsible for this difference, but conceded that this hypothetical effect "had not been observed previously in any clinical studies . . . ." App. at 765. Merck also stated that all other Vioxx trials "showed no indication of a difference in the incidence of thromboembolic events between Vioxx, placebo and comparator NSAIDs." App. at 766.

Securities analysts and the press duly reported the results of VIGOR and the naproxen hypothesis. For instance, an article published in Bloomberg News a month after the VIGOR results were released reiterated Merck's hypothesis about naproxen's effect on platelet aggregation, but noted that "[n]aproxen doesn't have documented protective effects on the heart," and quoted an analyst who stated, "that Vioxx increases cardiac risk . . . may be true, but it is far too soon to make that kind of judgment." App. at 2292. Similarly, a J.P. Morgan report from April 2000 noted the intuitive appeal of the theory that "the thromboembolic event issue is an 'NSAID-issue,'" but explained that the "theoretical cardiovascular protective benefits of Naprosyn . . . have not been clinically proven . . . ." App. at 2376. In another article, a spokesperson for the makers of Naprosyn stated, "[t]o our knowledge, naproxen does not prevent heart attack or stroke . . . ." App. at 2288. In our view, this category of disclosures does not constitute storm warnings that Merck misrepresented Vioxx's safety profile to investors in a manner that might give rise to a securities fraud claim. On the contrary, securities analysts and the press recognized the naproxen hypothesis for what it was, an unproven hypothesis.

and recognized that there was an alternative hypothesis, "that Vioxx increases cardiac risk . . . ." App. at 2292.

Shortly before the AAC hearing, during which the FDA considered how Vioxx's labeling should be modified to incorporate the results of the VIGOR study, a J.P. Morgan research report described the effect of NSAIDs such as naproxen on CV events as "poorly proven" and explained that there was "no way to retrospectively slice the data to prove the NSAID benefit vs. Vioxx risk argument . . . ." App. at 2547. At that hearing, defendant Reicin, the Executive Director of Clinical Research at Merck Research Laboratories, who argued in support of the naproxen hypothesis, admitted at the outset that the explanation for the results of the VIGOR study was uncertain. The first Vioxx product liability lawsuit (which, incidentally, charged the makers of Celebrex with identical wrongdoing) followed shortly thereafter, seeking "additional medical labeling which is presently being considered by the FDA [in conjunction with the AAC hearing.]" App. at 1748. Of course, investors, unlike Vioxx patients, were presumed to be aware of the publicized outcomes of research studies, such as VIGOR, which underlay the allegations of that product liability lawsuit. See Benak, 435 F.3d at 401 (explaining that "a direct investor . . . can be deemed to have consistent knowledge of his or her securities holdings").

The JAMA article evaluated Vioxx and Celebrex, both COX-2 selective inhibitors, together; its findings were not limited to Vioxx. The article concluded, based in part on VIGOR, that "[c]urrent data would suggest that use of selective COX-2 inhibitors might

lead to increased cardiovascular events." App. at 752. Of course, this is simply the alternative to the naproxen hypothesis. The JAMA article did not present any data that would suggest that Merck did not have reason to propose that hypothesis. Accordingly, it is of little surprise that a Deutsche Banc securities analyst described the types of questions raised in the JAMA article as "not new news . . . ." App. at 2749. Moreover, Merck issued reassuring statements the day before and the day after the article was published. Again, we are of the view that the JAMA article, taken on its own, did not constitute sufficient information of possible wrongdoing under the securities laws so as to raise a storm warning of culpable activity under the securities laws.

The FDA warning letter demands more scrutiny. In analyzing the effect of that letter through the prism of inquiry notice, we must not lose focus of the nature of the allegations in the letter and the scope of the FDA's regulatory authority. The FDA targeted Merck's "promotional campaign for Vioxx," App. at 713, under its authority to regulate prescription drug advertisements, see 21 U.S.C. § 352(n); see generally Pa. Employees Benefit Trust Fund v. Zeneca Inc., 499 F.3d 239, 248-49 (3d Cir. 2007) (discussing the FDA's authority over prescription drug advertising). The letter focused on three distinct components of the promotional campaign that the FDA found of concern: (1) six promotional audio conferences, presumably aimed at health care professionals such as doctors and pharmacists; (2) a press release dated May 22, 2001 entitled "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx," App. at 718;

and (3) oral representations made by Merck sales representatives, again, presumably to health care professionals. The FDA chastised Merck's promotional campaign for "discount[ing] the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on" naproxen, and "selectively present[ing]" the naproxen hypothesis as the reason for the incidence of increased CV events. App. at 713. The FDA stated that Merck's promotional campaign "fail[ed] to disclose that [its] explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have prothrombotic properties." App. at 713. For a number of reasons, we are hesitant to conclude that the FDA warning letter was sufficient to trigger inquiry notice.

To begin with, the FDA was acting as a regulator of drug advertising, rather than as a regulator of the securities markets. Thus, contrary to Merck's contention at oral argument, the FDA's actions are hardly analogous to allegations of accounting fraud issued by the SEC, which regulates the securities markets. Indeed, the FDA's drug advertising regulations and the securities laws provide wholly different standards with respect to what constitutes a misrepresentation. FDA regulations provide that advertisements must not be "lacking in fair balance," 21 C.F.R. § 202.1(e)(6), and prohibit advertisements that "[c]ontain[] a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience . . . or

otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated," id. § 202.1(e)(6)(iv). In contrast, under the securities laws, "a fact or omission is material only if 'there is a substantial likelihood that it would have been viewed by the reasonable investor as having significantly altered the "total mix" of information' available to the investor." In re NAHC, 306 F.3d at 1330 (quoting Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)).

Second, the FDA's description of the truth about the VIGOR study is quite similar to the evidence that Merck had long acknowledged and which the market had incorporated. Specifically, the FDA stated that the naproxen hypothesis "is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties." App. at 713. This information is implicit in Merck's long-standing admission that the posited anti-coagulant effect of naproxen "on [CV] events had not been observed previously in any clinical studies for naproxen." App. at 765. On the basis of Merck's public announcements, securities analysts discussed the existence of "a 'Vioxx risk' hypothesis" over seven months before the FDA warning letter was issued. App. at 2547. Indeed, the FDA did not charge that the naproxen hypothesis was wrong or that Merck did not believe in the validity of its hypothesis; rather, the agency simply directed Merck to be more clear about the widely known alternative hypothesis in its dealings with health care professionals and, presumably, consumers.

Third, two of the three components of the promotional campaign subject to the FDA's reprimand consisted of statements made to health care professionals in the course of targeted audio conferences and personal conversations. The third component of the promotional campaign targeted by the FDA was the press release, but that press release merely repeated the same information that was first contained in the VIGOR press release, i.e., "significantly fewer heart attacks were observed in patients taking naproxen . . . compared to the group taking Vioxx," "the VIGOR finding is consistent with naproxen's ability to block platelet aggregation by inhibiting COX-1," "[t]his is the first time this effect of naproxen on cardiovascular events has been observed in a clinical study," and "[o]ther potential explanations" for the results were possible. Press Release, Merck & Co., Inc., Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx(R) (May 22, 2001) (available on PR Newswire and LexisNexis).

Finally, we consider the effect the FDA warning letter had on the market. Merck's stock price dipped slightly following the disclosure of the FDA warning letter before closing higher than it did before that disclosure just a week and a half later. Although the lack of significant movement in Merck's stock price following the FDA warning letter is not conclusive, it supports a conclusion that the letter did not constitute a sufficient suggestion of securities fraud to trigger a storm warning of culpable activity under the securities laws. See, e.g., Berry, 175 F.3d at 705 (asserting that the "negligible impact" of an alleged storm warning on defendant's stock price bolstered

conclusion that inquiry notice was not triggered). This conclusion is also supported by the fact that more than a half-dozen securities analysts continued to maintain their ratings for Merck stock and/or project increased future revenues for Vioxx after the warning letter was made public.

Merck also emphasizes the three additional lawsuits filed after the FDA warning letter. Of course, none of these lawsuits alleged securities fraud. Rather, they alleged consumer fraud, product liability, and personal injury claims. The claims in those lawsuits alleged that Merck failed to provide publicly available information to Vioxx consumers, rather than to Merck investors. Cf. In re Ames Dep't Stores, Inc. Note Litig., 991 F.2d 968, 980 (2d Cir. 1993) (stating that the different concerns of debt and equity holders may call for distinct inquiry notice dates for the two classes of investors).

Finally, we question the District Court's conclusion that the New York Times article constituted a storm warning. The District Court reasoned that defendant Scolnick's statements in that article constituted "a significant departure from Merck's company line as to the explanation for the VIGOR study results." In re Merck, 483 F. Supp. 2d at 420. But Scolnick did not abandon the naproxen hypothesis; rather, he reiterated that Merck "found no evidence that Vioxx increased the risk of heart attacks" when it looked back at its data comparing Vioxx to other drugs and placebos and "that 'the likeliest interpretation of the data is that naproxen lowered . . . the thrombotic event rate' . . . ." App. at

654.[15] Even in the wake of the FDA warning letter, then, Merck continued to reassure the investing public that Merck stood behind the naproxen hypothesis, while acknowledging that another explanation (i.e., that Vioxx causes CV events) remained a possibility. See Benak, 435 F.3d at 402 n.16 ("Reassurances can dissipate apparent storm warnings if an investor of ordinary intelligence would reasonably rely on them to allay the investor's concerns.") (citation and internal quotation marks omitted). It is also notable there was no "significant movement" of Merck's stock price following the article's publication. Newman, 335 F.3d at 195. Thus, we cannot conclude as a matter of law that this article constituted a storm warning.

In summary, we conclude that the District Court acted prematurely in finding as a matter of law that Appellants were on inquiry notice of the alleged fraud before October 9, 2001. As of that date, market analysts, scientists, the press, and even the FDA agreed that the naproxen hypothesis was plausible, at the very least. None suggested that Merck believed otherwise. Accordingly, in April 2002, the FDA approved a labeling change for Vioxx which stated that "[t]he significance of the cardiovascular findings [from the VIGOR study] is unknown." App. at 553. Merck continued to reassure the investing public at this time, explaining that the naproxen

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[15] The New York Times article also explained that "[t]he risk is hypothesized, not proved," and that "leading arthritis specialists . . . say that they are not concerned and that they prescribe the drugs for patients who may have heart disease." App. at 653.

hypothesis was "a position Merck has always had and now its [sic] quite clearly laid out in the labeling." App. at 559. On the record before us, there is no reason to suspect that Merck did not believe the naproxen hypothesis until the Harvard study in 2003 revealed an increased risk of heart attack in patients taking Vioxx compared with patients taking Celebrex and placebo. This study for the first time belied Merck's repeated assurances that naproxen was responsible for the disparity in CV events in VIGOR and that Vioxx did not have a higher incidence of CVs compared to placebo or comparator NSAIDs, such as Celebrex.[16]

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[16] There are two statements in the dissent, although arguably going to minor issues, that call for a response. The dissent states that Scolnick's statement quoted in the October 9, 2001 New York Times article was "the first time [the statement that the VIGOR results could be explained by either the effect of naproxen or Vioxx] had been made by the company." Dissent Typescript op. at 46-47. In fact, as noted above, Alise Reicin, the Executive Director of Clinical Research at Merck Research Laboratories, had testified as to that possibility at the FDA's hearing before the AAC as early as February 8, 2000, more than eight months before the New York Times article. See supra p. 7.

Second, to the extent that the dissent suggests that the majority holds that fluctuations in stock price and analysts' ratings and projections are necessary to a finding of storm warnings, Dissent Typescript op. at 47, a rereading of the majority opinion will make clear that the majority agrees with the dissent that such factors are relevant to the storm warnings inquiry, but not required. See supra p. 28.

It is ironic that the dissent, although noting what might be viewed as Merck's misrepresentations, would apply the

V.

Conclusion[17]

For the reasons set forth, we will reverse the judgment of dismissal and remand to the District Court for further proceedings consistent with this opinion.

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statute of limitations to deprive plaintiffs of the opportunity to prove a viable case against Merck for such misrepresentations.

[17] Because we have concluded that the District Court erred in finding Appellants on inquiry notice of the alleged fraud at this stage of the litigation, we do not address Appellants' remaining arguments regarding the claims of plaintiffs who purchased stock after October 9, 2001 and the viability of Appellants' section 20A claims.

In re: Merck & Co., et al.

Nos. 07-2431/2432

ROTH, Circuit Judge, dissenting.

I believe "storm warnings" alerting a reasonable investor of *possible* culpable activity on the part of Merck were evident more than two years prior to the filing of appellants' complaint. In particular, I believe that the FDA's September 17, 2001, warning letter, in and of itself, provided sufficient "storm warnings" to put the appellants on inquiry notice of their claims regardless of any significant change in stock price or analysts' stock ratings or projections at that time. I therefore respectfully dissent.

Under the "inquiry notice" test, the statute of limitations for securities claims "begins to run when the plaintiffs 'discovered or in the exercise of reasonable diligence should have discovered the basis for their claim' against the defendant." *Benak v. Alliance Capital Management L.P.*, 435 F.3d 396, 400 (3d Cir. 2006) (*quoting In re NAHC, Inc. Securities Litigation*, 306 F.3d 1314, 1325 (3d Cir. 2002) (citations omitted)). In order to establish that plaintiffs were on inquiry notice, a defendant must demonstrate that, as of a particular date, there existed "storm warnings" sufficient to alert "a reasonable investor of ordinary intelligence" to "*possible* wrongdoing" on the part of defendants. *Id.* (*quoting In re NAHC*, 306 F.3d at 1325) (explaining that the question is whether plaintiffs had "sufficient information of possible wrongdoing to place them on

'inquiry notice' or to excite 'storm warnings' of culpable activity") (emphasis added).

Furthermore, it is well established that "[t]he existence of storm warnings is a *totally objective* inquiry[,]" that is based on whether a "reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning[.]" *Mathews v. Kidder Peabody & Co., Inc.*, 260 F.3d 239, 252 (3d Cir. 2001) (emphasis added); *see also In re NAHC*, 306 F.3d at 1325. We do not require that plaintiffs "know all of the details or 'narrow aspects' of the alleged fraud to trigger the limitations period[,]" but rather "the period begins to run from the time at which plaintiff should have discovered the general fraudulent scheme." *In re NAHC*, 306 F.3d at 1326 (internal quotations and citations omitted). Most importantly, we recognize that triggering data for "storm warnings" may include any information that would alert a reasonable investor to the *possibility* that the defendants engaged in the "*general fraudulent scheme*" alleged in the complaint. *Id.* (emphasis added). Finally, such triggering data must "relate[] directly to the misrepresentations and omissions alleged." *DeBenedictis*, 492 F.3d at 217-18 (*quoting Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 171 (2d Cir. 2005)).

In applying the above inquiry notice standard to the instant case, I am reminded of a classic fairytale: *The Emperor's New Clothes*, by Danish author and

poet, Hans Christian Anderson.[18] As the child in *The Emperor's New Clothes* saw – that the Emperor walked naked down the street – any reasonable investor reading the FDA's September 17, 2001, warning letter could see the problem with Vioxx – the misrepresentation of its safety profile and the "possibility" that Merck had fraudulently misrepresented the cardiovascular safety of its "blockbuster" product. The warning letter to Merck, which was published on the FDA's public website, stated in pertinent part:

> *You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings* that were observed in the [VIGOR] study, and *thus, misrepresents the safety profile* for

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[18] In the story, two swindlers approached the Emperor, falsely claiming the ability to make beautiful clothes from cloth that could be seen only by those individuals fit for their positions or who were not imbecils. The Emperor immediately hired them. Word spread throughout the city about the unique quality of the cloth and the personal characteristics that an individual must possess to see clothes made of such material. After the swindlers finished weaving the Emperor's new clothes and presented them to him, neither the Emperor nor his most trusted servants would admit that they could not see the clothes for fear of appearing unfit or stupid. Instead, each exclaimed that the clothes were beautiful. Donning his new clothes, the Emperor walked in a procession through the city's streets. The townspeople also feared looking stupid in their neighbors' eyes. Like the Emperor and his servants, they proclaimed that the clothes were the most beautiful they had ever seen. It wasn't until a child exclaimed, "But, Daddy, he has nothing on!" that the crowd realized that the child spoke the truth.

Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator [NSAID], Naprosyn (naproxen).

Although the exact reason for the increased rate of MIs observed in the Vioxx treatment group is unknown, your promotional campaign selectively presents the following hypothetical explanation for the observed increase in MIs. *You assert that Vioxx does not increase the risk of MIs and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin.* That is a possible explanation, but *you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties.*

...

Your *minimizing* these potential risks and *misrepresenting* the safety profile for Vioxx *raise significant health and safety concerns.* Your *misrepresentation* of the safety profile for Vioxx is *particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for Vioxx that also misrepresented Vioxx's safety profile.*

> ...
> We have identified a Merck press release entitled, "Merck Confirms Favorable Cardiovascular Safety Profile of VIOXX," dated May 22, 2001, that is also *false or misleading* for similar reasons stated above. Additionally, *your claim in the press release that VIOXX has a "favorable cardiovascular safety profile," is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDs is misleading;* in fact, serious cardiovascular events were twice as frequent in the VIOXX treatment group (101 events, 2.5%) as in the naproxen treatment group (46 events, 1.1%) in the VIGOR Study.

App. at 713-14, 718 (emphasis added).[19]

The warning letter *clearly and explicitly* reprimanded Merck for its (1) deceptive and misleading conduct in publicly endorsing the

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[19] Also in the warning letter, the FDA identified specific statements made by Merck in promotional audio conferences and by Merck's sales force demonstrating Merck's minimization and misrepresentation of the increased heart attack rates of Vioxx-taking participants in the VIGOR study and several unsubstantiated superiority claims made by Merck about Vioxx. App. at 715-16, 718-19. Finally, the warning letter concluded with a corrective action plan which required Merck to issue a "'Dear Healthcare provider' letter to correct false or misleading impressions and information." App. at 719.

naproxen hypothesis as the sole explanation for the higher rate of cardiovascular events in VIGOR study participants taking Vioxx, *despite* knowing that any purported cardiovascular protective effect of naproxen was unproven, and (2) downplaying of potential safety problems in failing to disclose the possibility that Vioxx increases the risk of heart attack. As the letter explained, this was *not* the first time the FDA had charged Merck with misrepresenting Vioxx's safety profile. The language used in the letter was particularly strong and indicated the FDA's significant concern for the public's health. Also, the warning letter cannot be said to have constituted mere speculation, but was rather a formal report of "objective wrongdoing." *See Benak*, 435 F.3d at 402 (explaining that, in determining whether a plaintiff has inquiry notice, "[s]peculation should not be given the same weight as reports of objective wrongdoing"). Furthermore, the warning letter was published on the FDA's website where it would have been discovered by a reasonable Merck investor. *See In re NAHC*, 306 F.3d at 1325.

Moreover, the charges in the warning letter relate directly to the misrepresentations and omissions alleged in the appellants' complaint: that the company and certain of its officers and directors intentionally misrepresented the cardiovascular safety of Vioxx and, consequently, the impact that Vioxx would have on Merck's financial health. *See DeBenedictis*, 492 F.3d at 217-18; *see e.g.*, Amended Complaint, App. at 468 (stating that "Defendants made... materially false and misleading statements and omissions concerning... the safety profile of...

VIOXX"); App. at 470 (stating that "Defendants misrepresented the safety profile of VIOXX, including concealing and minimizing the significantly increased risk of heart attacks in patients taking the drug"); App. at 482 (describing a "wrongful scheme... which included the dissemination of materially false and misleading statements and concealment of material adverse facts"); App. at 497 (stating that "Defendants falsely conditioned the market to believe VIOXX was safe"). Accordingly, I believe that the FDA's warning letter to Merck sufficiently alerted a reasonable investor to the *possibility* that Merck fraudulently misrepresented the cardiovascular safety of Vioxx – its "blockbuster" product.[20]

Even assuming that the FDA's warning letter alone did not sufficiently excite "storm warnings,"

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[20] It is important to note that Merck's reliance on its naproxen hypothesis was proved to be unfounded from the beginning. Even before the FDA's warning letter was issued, an April 27, 2000, *Reuters* article reported that (1) a spokesperson for leading naproxen manufacturer, Roche Holding Ltd., explained that "[t]o [their] knowledge, naproxen does not prevent heart attack or stroke" and (2) an ABN Amro analyst indicated that "[m]edical authorities [he had] spoken to don't see any special reduction of such cardiovascular events in people taking naproxen." App. at 2288. Additionally, an August 21, 2001, *Bloomberg News Article*, reported a Merck representative's comment that "[Merck] already ha[s] additional data beyond what [the *JAMA* article] cite[s], and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo." App. at 539. Even if this "additional data" included evidence that could support Merck's naproxen hypothesis, Merck never revealed the details of its purported "additional data."

the total mix of information in the public realm which followed the warning provided more than adequate "storm warnings" to put appellants on inquiry notice.

In response to the FDA's warning letter, there was widespread media and financial analyst coverage commenting on the FDA's charges against Merck, with some reports noting that such warnings are reserved for the more serious offenders. *See e.g.*, App. at 2353 (*Reuters*, September 24, 2001) (reporting that "U.S. Regulators have charged... Merck... with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks"); App. at 2752 (*Merrill Lynch*, September 24, 2001) (stating that "[t]he FDA issued a warning letter to Merck... [and] is looking for Merck to cease all violative promotional activities... . We do not see how this... can be helpful to Merck in promoting Vioxx"); App. at 2355 (*USA Today*, September 25, 2001) (reporting that "Merck's marketing efforts... have minimized Vioxx's known and potential cardiovascular risks, the FDA wrote in an eight-page 'warning letter'... . So far this year, the FDA has sent drug companies fewer than a dozen warning letters, which the agency reserves for activities that raise significant public health concerns"); App. at 2768 (*UBS Warburg*, September 25, 2001) (stating that the "FDA [has] issue[d] [a] warning to Merck for marketing only one side of the Vioxx safety argument... . Merck was cited several times for promoting the story that the outcome of the VIGOR study was due to Naproxen being cardioprotective and that there is no unusual cardiovascular safety

risk with Vioxx."); App. at 2360 (*Associated Press*, September 25, 2001) (reporting that "Merck has argued that [the VIGOR study results make] Vioxx falsely look[] risky because naproxen thins the blood... and thus protect[s] against heart attacks... . 'In fact, the situation is not all that clear,' [according to] the FDA"); App. at 2757 (*Credit Suisse First Boston*, September 25, 2001) (stating that "the FDA [has] issued a warning letter citing Merck with making misleading statements in the promotion of... Vioxx"); App. at 2361 (*The Wall Street Journal*, September 25, 2001) (reporting that "Federal regulators warned Merck & Co. for improper marketing of its blockbuster arthritis drug Vioxx, saying the company had misrepresented the drug's safety profile and minimized its potential risks[,]" and "[w]hile the FDA sends out dozens of routine citations annually, it issues only a handful of these more-serious warning letters each year"); App. at 2363 (*The New York Times*, September 26, 2001) (stating that "[t]he [FDA] has ordered Merck & Company to cease promotions intended to persuade doctors to prescribe its arthritis painkiller Vioxx, saying the promotions minimize potential risks"). Even appellants themselves recognized in their complaint that "FDA Warning Letters are sent only to address serious circumstances." App. at 1280.

Furthermore, in addition to the first lawsuit filed before the FDA's warning letter, three product liability and consumer fraud actions had been filed in September and October 2001, all alleging that Merck had misrepresented the cardiovascular safety of Vioxx. *See* App. at 1748 (May 29, 2001, product liability class action alleging that "Merck's own

research [demonstrated that] users of Vioxx were four times as likely to suffer heart attacks as compared to other less expensive medications..., [but that] Merck... [took] no affirmative steps to communicate this critical information to class members"); App. at 1557 (September 27, 2001, consumer fraud class action alleging that "Merck [had] omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Vioxx, including... cardiovascular problems... [and] purposely downplayed and/or understated the serious nature of the risks associated with Vioxx"); App. at 1574 (September 28, 2001, product liability and consumer fraud action alleging that Merck had "misrepresented that Vioxx was... safe and effective.... when in fact the drug causes serious medical problems such as an increased risk of cardiovascular events, including strokes, heart attacks and death"); App. at 1611 (October 1, 2001, product liability action alleging that Merck failed to "[]disclose[]" that "Vioxx causes heart attacks"). While these law suits did not allege *securities* fraud, the general allegations contained within these complaints relating to Merck's intentional misrepresentation with regard to Vioxx's safety similarly formed the basis of appellants' complaint.

Moreover, *The New York Times* article, dated October 9, 2001, quoted defendant Scolnick as explicitly stating that "[n]aproxen lowers the heart attack rate, *or Vioxx raises it*." App. at 2367 (emphasis added). Based on my review of the record, this express acknowledgment by a Merck representative of the possibility that Vioxx actually

raises the risk of heart attack appears to be not only the first time such statement had been made by the company, but also in stark contrast to Merck's prior representations. Therefore, because of what I perceive to be significant media and financial analyst attention directed at the explicit and serious nature of the FDA's warning letter, the allegations in the multiple lawsuits which followed, and Merck's change of tone in the October 9, 2001, article, I cannot see how a reasonable investor could not be aware of the *possibility* that Merck had been fraudulently misrepresenting the cardiovascular safety of Vioxx.

Because the objective evidence indicated the possibility of culpable activity on the part of Merck, a lack of significant stock movement and decreases in analysts' stock ratings and projections *do not negate* a finding of "storm warnings" under our inquiry notice standard. Appellants argue that "storm warnings" could not have existed prior to the 2003 Harvard Study because the total mix of public information did not have a negative effect on the price of Merck stock or cause analysts to drop their ratings for Merck or lower their projections for Vioxx sales. It is true, as the majority points out, that our past inquiry notice decisions have taken into consideration the market's response to disclosures alleged to constitute "storm warnings." However, I do *not* believe the law *requires* that, in order to make a determination that "storm warnings" in fact exist, the total mix of public information (purported to constitute "storm warnings") *must* have a negative effect on stock prices or cause analysts to drop their ratings or lower their projections. *See Benack*, 435

F.3d at 400 ("information [need only suggest] *possible* wrongdoing... to excite 'storm warnings'") (*quoting In re NAHC*, 306 F.3d at 1325) (emphasis added). As we recognized in *In re NAHC*:

> [S]torm warnings may take numerous forms, and we will not attempt to provide an exhaustive list. They may include, however, substantial conflicts between oral representations of the brokers and the text of the prospectus, ... the accumulation of information over a period of time that conflicts with representations that were made when the securities were originally purchased, *or any financial, legal or other data that would alert a reasonable person to the probability that misleading statements or significant omissions had been made.*

306 F.3d at 1326 n.5 (quoting *Mathews*, 260 F.3d at 252 (internal citations and quotations omitted)) (emphasis added). In my view, fluctuations in stock price and analysts' ratings and projections, although relevant, are *not* a *required* consideration in this circuit's objective "storm warnings" analysis. Here, the lack of a significant response from the market to the FDA's warning letter does not mean that the Emperor was not walking down the street with no clothes on. It merely means that the analysts saw the emperor's new clothes as Merck described them – not as reality presented.[21]

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[21] Regardless, Merck's stock price did decline sharply in the months leading up to October 9, 2001, as the public

Based on the foregoing, I submit there were sufficient "storm warnings" more than two years prior to the filing of appellants' complaint. At a minimum, I believe the FDA's September 17, 2001, warning letter constituted more than sufficient "storm warnings" to put appellants on inquiry notice of their claims, particularly since appellants fail to demonstrate either that they conducted a diligent investigation within two years of the accrual of such "storm warnings" or that they were unable to uncover pertinent information during that time period. Accordingly, because appellants waited over two years to bring suit, I conclude that their claims were filed out of time and were properly dismissed by the District Court.

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controversy about Vioxx raged. From January 1, 2001, to October 9, 2001, Merck's stock price declined by $24.32 or 27.4%. App. at 1770-73. As appellants themselves alleged, "Merck's stock price began its slide in approximately *January of 2001, and continued and worsened after August of 2001* when the VIGOR cardiovascular data was presented more fully in the [JAMA article]." App. at 1225 (emphasis added).

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE MERCK & CO., INC. SECURITIES, DERIVATIVE & "ERISA" LITIGATION	**MDL No. 1658 (SRC)**
THIS DOCUMENT RELATES TO: THE CONSOLIDATED SECURITIES ACTION	**Civil Action No. 05-1151 (SRC)** **Civil Action No. 05-2367 (SRC)**
	OPINION

CHESLER, District Judge

This matter comes before the Court upon two motions to dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint ("Complaint") covering all Defendants in this case. The matter was opened by the motion to dismiss brought by Defendants Merck & Co., Inc., Raymond V. Gilmartin, Kenneth C. Frazier, Richard C. Henriques, Jr., Peter S. Kim, Judy C. Lewent, Alise S. Reicin, Lawrence A. Bossidy, William G. Bowen, Johnetta B. Cole, William B. Harrison, Jr., William N. Kelley, Heidi G. Miller, Thomas E. Shenk, Anne M. Tatlock, Samuel O. Thier, David Anstice, Richard T. Clark, Celia Colbert, Linda M. Distlerath, Caroline Dorsa, Bernard J. Kelley, Per G. H. Lofberg, Per Wold-Olsen and Lloyd C. Elam (hereinafter, these Defendants will be referred to collectively as "Merck") (docket item # 14). Defendant Dr. Edward M. Scolnick separately filed a motion to dismiss (docket item # 13). Upon being served, Defendant

Niall Fitzgerald joined in Merck's motion to dismiss (docket item #162) and therefore, will hereinafter be encompassed within the Court's collective reference to various defendants as "Merck." The motions seek dismissal on numerous grounds, including the running of the statutes of limitation. For the reasons that follow, the Court grants the motions and dismisses the Complaint as time-barred. Because the Court has determined that Plaintiffs' claims are untimely, the Court will not address the other arguments raised by Defendants in the motions to dismiss.

I. BACKGROUND

This securities fraud class action concerns alleged misrepresentations and omissions made by Defendants about the safety profile of Merck's prescription drug VIOXX. Plaintiffs allege that Merck and Dr. Scolnick[1] concealed information that suggested or demonstrated that VIOXX significantly increased the risk of heart attack or other cardiovascular event and made misleading statements about the drug's safety. Plaintiffs, who purchased Merck securities during the time period from May 21, 1999 through October 29, 2004, allege that they bought the securities at prices that were

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[1] Dr. Scolnick was Merck's Executive Vice President for Science and Technology and President for Merck Research Laboratories from the beginning of the Class Period (May 21, 1999) through December 31, 2002, when he retired. From January 1, 2003 through the end of the Class Period (October 29, 2004), Scolnick served as President Emeritus, Merck Research Laboratories.

artificially inflated due to Defendants' fraud. The earliest securities fraud complaint was filed on November 6, 2003.

A. VIOXX Research and Safety Concerns

VIOXX, generically known as rofecoxib, is a nonsteroidal anti-inflammatory drug ("NSAID"). It was introduced to the market on May 21, 1999. In May 2001, the Federal Food and Drug Administration ("FDA") approved VIOXX for treating primary dysmenorrheal (severe menstrual cramps), managing acute pain in adults, and relieving symptoms relating to osteoarthritis. Merck promoted VIOXX as having a safety profile superior to other NSAIDs. Specifically, unlike traditional NSAIDs, which include aspirin, ibuprofen and naproxen, VIOXX did not cause serious gastrointestinal side effects. Whereas traditional NSAIDs operate by inhibiting two enzymes - cyclooxygenase-1 ("COX-1") and cyclooxygenase-2 ("COX-2") - VIOXX selectively suppresses only COX-2 without affecting COX-1. This is significant because the suppression of COX-1 can lead to the deterioration of the stomach lining and gastrointestinal problems such as perforations and bleeds.

Merck continued to research, study and test VIOXX after its approval by the FDA and introduction to the market. One of these studies was Study 088, which the Court highlights because of its relevance to the facts on which the Court bases its decision on the motions to dismiss. In January 1999, Merck commenced Study 088, known as the VIOXX GI Outcomes Research ("VIGOR") study, to continue to examine VIOXX's gastrointestinal safety profile.

Participants received either a daily dose of VIOXX at 50mg a day (twice the maximum recommended and approved chronic dose) or naproxen at 1000mg a day (a standard dose). Upon completion of the VIGOR study in March 2000, Merck made a public disclosure about the study in a March 27, 2000 press release. Among other things, the VIGOR study showed that thrombotic events, including myocardial infarction (heart attack), occurred in more patients in the VIOXX treatment group than in the naproxen treatment group. In relevant part, the March 27, 2000 press release stated that

> significantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation. This effect on these events had not been observed previously in any clinical studies for naproxen.

(Baron Decl., Ex. 5.) In other words, Merck took the position that the difference in thrombotic event rates between VIOXX and naproxen was due to a cardioprotective effect of naproxen (also known as the "naproxen hypothesis"). Significantly, according to the allegations made by Plaintiffs, Merck was aware that there was another explanation for the difference in thrombotic event rates in the VIGOR study's treatment groups, that is, that VIOXX had pro-thrombotic properties, or, in other words, that VIOXX increased the risk of a thrombotic event such as a heart attack.

On June 29, 2000, Merck submitted VIGOR data and analysis to the FDA. On February 8, 2001 the

FDA's Arthritis Advisory Committee held a public hearing to discuss VIOXX's gastrointestinal and cardiovascular safety. Merck presented the naproxen hypothesis as the best explanation for the VIGOR results. The Committee found that VIGOR did not conclusively establish a link between VIOXX and cardiovascular risk. It also concluded, however, that Merck should include on the VIOXX label data about the higher incidence of cardiovascular events observed in the VIGOR study. A consultant to the Arthritis Advisory Committee on this issue and a member of the Cardiovascular and Renal Drugs Advisory Committee, Dr. Steven Nissen, stated:

> Briefly, I think what I would say in the label is that there was an excess of cardiovascular events in comparison to naproxen, that it remains uncertain whether this was due to beneficial cardioprotective effects of naproxen or prothrombotic effects of the agent, and leave it at that, that basically we don't know the reason. We do know that there was a difference. That awareness should be made available to the prescriber and to the consumer, but without necessarily a final judgment as to the reasons for that difference.

(Id., Ex. 10, at 210:5-14.)

The VIGOR study initiated a public debate about the naproxen hypothesis versus the hypothesis that VIOXX increased cardiovascular risks. The issue received extensive coverage from the press, scientific publications, and financial analysts. In a

November 23, 2000 article authored by both Merck and non-Merck scientists, the New England Journal of Medicine published the results of the VIGOR study; the article attributed the higher incidence of thrombotic events in VIOXX patients relative to naproxen patients to the purported cardioprotective effect of naproxen without raising the alternate explanation of increased risk due to VIOXX. (Id., Ex. 6.) Many financial analyst reports and articles published in scientific and medical literature as well as general news publications questioned Merck's interpretation of the VIGOR data. An April 27, 2000 report by Reuters cast doubt on "Merck's suggestion that naproxen conferred protection against heart attacks and strokes" and quoted Roche Holding, Ltd., a manufacturer of naproxen, as stating: "To our knowledge, naproxen does not prevent heart attack or stroke." (Id., Ex. 89). Following the February 8, 2001 FDA hearing, a February 9, 2001 article in USA Today stated that "[arthritis patients] should know that the blockbuster drug [VIOXX] might increase their risk of suffering a heart attack." (Id., Ex. 105.) On May 2, 2001, The New York Times also reported on the higher risk of heart attack for patients taking VIOXX. (Id., Ex. 106).

An article published in the August 22, 2001 Journal of the American Medical Association ("JAMA") reported results of a study of VIOXX and Celebrex conducted by the Cleveland Clinic. It stated: "Current data suggest that the use of selective COX-2 inhibitors might lead to increased cardiovascular events." (Id., Ex. 3, at 958.) The article's authors argued that the data raised a "cautionary flag" about the risk of cardiovascular

events with selective COX-2 inhibitors, such as VIOXX. (Id. at 954.) With regard to the VIGOR study, the article commented that "[t]he results of the VIGOR study can be explained by either a significant prothrombotic effect from rofecoxib or an antithrombotic effect from naproxen (or conceivably both)." (Id. at 957.) The JAMA article received extensive coverage in other publications, including mainstream news sources.

On the other hand, other news and analyst reports during the same 2000 to 2001 time period reinforced the naproxen hypothesis as the correct interpretation of the VIGOR data or minimized the concern raised about VIOXX's possible pro-thrombotic properties. Examples of such information include the following:

April 12, 2000 Biotech Week article entitled "Merck & Co., Inc.: Preliminary Results of Gastrointestinal Outcomes Study Presented"

> "Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and would not be expected to have similar effects. Medicines like aspirin and naproxen that significantly inhibit COX-1 block platelet aggregation and therefore have the potential to provide cardioprotection."

April 28, 2000 Dow Jones article

> "[A]t least one analyst - and the company - said there's little to worry about. 'This whole thing has been

> overblown and taken out of context,' says Wall Street Journal All-Star analyst Jeff Chaffkin of PaineWebber. 'We had this data over four weeks ago. This is nothing new.'"

May 1, 2000 Bernstein Research analyst report

> "We'd be shocked if [the] FDA gave this a second glance, much less re-labeled VIOXX to suggest greater risks of vascular events. It's not VIOXX increasing events, it's Naproxen reducing them."

February 8, 2001 Bloomberg News article entitled "Merck Drug Should Note Heart Risk, Stomach Benefit, Panel Says"

> "Differences in cardiac risk between Vioxx and naproxen appeared to result from a beneficial effect of naproxen, not a danger from Vioxx, said Nigel Harris, the [FDA Arthritis Advisory Committee] panel's chairman and the dean of the department of internal medicine at Morehouse School of Medicine."

August 22, 2001 Credit Suisse First Boston analyst report

> "The JAMA researchers themselves point out several significant limitations in their study . . . We note that the VIGOR trial did not include low-dose

> aspirin, and that the control drug (naproxen) is known to possess a cardio-protective, anti-platelet effect. This makes it extremely difficult to determine whether the difference in cardiac events seen in VIGOR results from a naproxen 'benefit' or a Vioxx 'liability.'"

Merck did not remain silent in this public debate, and Plaintiffs highlight the consistent assurances Merck offered about the safety of its VIOXX product. All the while that certain media and financial analyst reports raised concern about whether VIOXX in fact increased the risk of heart attack, Merck disseminated positive information about the product, promoting its overall safety. In general, the statements attributed VIGOR data solely to the cardioprotectiveness of naproxen and/or discredited questions raised about the possibility that VIOXX is prothrombotic. Numerous press releases issued by Merck stated that VIOXX had an "excellent safety profile" and a "favorable cardiovascular safety profile." (Compl., ¶¶ 143, 190, 202-04.) In a June 13, 2001 press release announcing the findings of an analysis combining data from 19 clinical studies, defendant Reicin, the Executive Director of Clinical Research at Merck, was quoted as stating that "results in the meta-analysis with VIOXX vs. naproxen are consistent with the ability of naproxen to block platelet aggregation, and, therefore, to act as an anti-platelet agent" – in other words, endorsing the naproxen hypothesis without disclosing that this explanation had not been confirmed and that the results may possibly be due

to a prothrombotic effect of VIOXX. (Id., ¶ 206.) In anticipation of the August 22, 2001 article in JAMA, Merck commented that "we already have additional data beyond what they cite, and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo." (Id., ¶ 214).

B. The FDA Warning Letter

The FDA also entered, and fueled, the public discussion. On September 17, 2001, the FDA issued a Warning Letter to Merck concerning Merck's promotion of VIOXX. The letter admonished Merck for misrepresenting the safety profile of VIOXX, downplaying the cardiovascular findings of the VIGOR study, and explaining the results by offering the naproxen hypothesis as if it were based in fact. The letter stated:

> You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal antiinflammatory drug (NSAID), Naprosyn (naproxen).

> Although the exact reason for the increase rate of MIs observed in the Vioxx treatment group is unknown, your promotional campaign selectively presents the following hypothetical explanation for the observed increase in MIs. You assert that Vioxx does not increase the risk of MIs and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx many have pro-thrombotic properties.
>
> * * *
>
> Your misrepresentation of the safety profile for Vioxx is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for Vioxx that also misrepresented Vioxx's safety profile.

(Baron Decl., Ex. 1 at 1-2.) In the Warning Letter, the FDA directed Merck to implement a corrective action plan, including ceasing the misleading promotion of VIOXX and issuing a letter to doctors to correct false information it had disseminated. (Id. at 7.)

The FDA Warning Letter was published on the FDA website on September 21, 2001. It received widespread media and analyst coverage. (Id., Ex. 58,

59.) Numerous articles appeared in well-known publications in late September and early October 2001. By way of example, the media reported as follows:

> September 24, 2001 Bloomberg News article entitled "Merck Misrepresents Safety of Vioxx, FDA Says in Warning Letter"
>
> "The [FDA] cited Merck for minimizing 'potentially serious' findings in a study that showed heart attacks were significantly more common among patients who took Merck's drug than in patients who were treated with an older generic pain killer called naproxen."
>
> September 24, 2001 Reuters News article entitled "Merck Vioxx Promotions Said Misleading on Safety"
>
> "U.S. Regulators have charged drug giant Merck and Co. Inc. with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks." The article specifically references the September 17, 2001 FDA Warning Letter.
>
> September 25, 2001 USA Today article entitled "FDA Sends a Warning Letter to Maker of Vioxx Painkiller"

"Merck's marketing efforts, aimed mainly at doctors, have minimized Vioxx's known and potential cardiovascular risks, the FDA wrote in an eight-page 'warning letter' faxed Sept. 17 to Raymond Gilmartin, president and chief executive officer."

September 25, 2001 Reuters News article entitled "Merck Slips After FDA Scolding on Vioxx Safety Claim"

"Shares of Merck & Co. fell on Tuesday after U.S. regulators accused the firm of making unsubstantiated claims about its hot-selling arthritis drug Vioxx and downplaying a possible risk of heart attack from taking the medicine." The Reuters piece also discusses the study results reported in the August 22, 2001 JAMA article.

September 25, 2001 Associated Press article entitled "FDA Says Merck Misleading on Vioxx Safety"

"Merck has argued that Vioxx falsely looked risky because naproxen thins the blood much like aspirin does and thus protected against heart attacks . . . 'In fact, the situation is not at all clear,' the FDA responded, saying no studies prove naproxen thins blood enough to explain the discrepancy."

September 25, 2001 Wall Street Journal article entitled "FDA Warns Merck for Vioxx Promotions"

> "The FDA said that the exact reason for the increased rate of heart problems [observed in Vioxx patients] isn't known, but that the Merck promotional campaign 'selectively' presented the hypothetical explanation that drugs used in comparisons with Vioxx help prevent heart problems – thus making Vioxx's rate of heart problems appear to be artificially inflated."

September 26, 2001 New York Times article entitled "National Briefing Science and Health: U.S. Warns Merck About Marketing Arthritis Drug"

> "The Food and Drug Administration has ordered Merck & Company to cease promotions intended to persuade doctors to prescribe its arthritis painkiller Vioxx, saying the promotions minimize potential risks."

The New York Times ran an article on October 9, 2001 regarding the possible cardiovascular risk posed by VIOXX. Although the article did make clear that VIOXX's propensity to increase the risk of heart attack had not been proven, it did report that the FDA had issued a warning letter requiring Merck to disclose the possibility of this risk. Importantly, the article quoted defendant Dr. Scolnick, the president of Merck Research Laboratories, regarding the

results of the VIGOR study: "'There are two possible interpretations,' Dr. Scolnick said. 'Naproxen lowers the heart attack rate, or Vioxx raises it.'" (Rolnick Cert., Ex. A.) According to the article, Dr. Scolnick said that Merck had reviewed its data and concluded that "the likeliest interpretation of the data is that naproxen lowered lowered [sic] the thrombotic event rate," but that now, with new questions raised, none of the findings to date prove that the issue is fully resolved. (Id.)

C. Other Lawsuits

In the meantime, lawsuits concerning VIOXX were initiated against Merck. The first product liability class action was filed on May 29, 2001 in the United States District Court for the Eastern District of New York by attorney David Boies. The Complaint alleged that "[a]s demonstrated by Merck's own research, users of Vioxx were four times as likely to suffer heart attacks as compared to other less expensive medications, or combinations thereof . . . Nonetheless, Merck . . . [has] taken no affirmative steps to communicate this critical information to class members." (Baron Decl., Ex. 33, ¶ 3.) Among other claims, the complaint asserted a failure to warn claim, which alleged that "Defendants failed to perform adequate testing prior to [the drug's] introduction in that adequate testing would have shown that patients taking Vioxx . . . had an increased risk of heart attacks than those patients taking more traditional nonprescription pain relief medication." (Id., ¶ 30.) It further averred that "the manufacturer[ ] knew or should have known that Vioxx . . . posed a greater risk to patients . . . ." (Id., ¶ 31.)

Additional suits were filed immediately after the publication of the FDA Warning Letter of September 17, 2001. One of these was a consumer fraud class action lawsuit filed in New Jersey state court on or about September 27, 2001. The New Jersey suit, captioned John Astin v. Merck & Co., Inc., concerned alleged misrepresentations and omissions of material fact by Merck regarding the pro-thrombotic properties of Vioxx. The Astin class action complaint pled for relief under New Jersey's Consumer Fraud Act and a common law fraud theory. It alleged as follows:

> Merck violated the Consumer Fraud Act . . . by engaging in unconscionable commercial practices, through deception, fraud, and making false promises and misrepresentations, including, but not limited to, the following:
>
> (1) Merck omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Vioxx, including, but not limited to, the risks of serious damage from cardiovascular problems. Furthermore, Merck has purposefully downplayed and /or understated the serious nature of the risks associated with Vioxx; . . .

(Id., Ex. 23, ¶ 32.) The Astin complaint relied on the FDA Warning Letter and on an August 22, 2001 Wall Street Journal article reporting on the study published in the JAMA article of the same date.

Another action, asserting both products liability and fraud claims, was filed in Utah state court in late September 2001 on behalf of 16 plaintiffs who alleged that Merck had intentionally and knowingly deceived users of Vioxx by concealing information about the possibility that Vioxx increases a patient's risk of suffering a heart attack or other cardiovascular event. The Utah action charged that "Evidence linking the subject drug formulations to significant edema, serious cardiovascular events, and death has been noted and reported in a large study (VIGOR) that was sponsored by Merck & Company, Inc. in 2000. These known material risks were not disclosed to or shared with Plaintiffs by Defendant." (Id., Ex. 24, ¶ 19.) The complaint relied on and quotes extensively from the FDA Warning Letter. It also quotes the August 22, 2001 JAMA article, an August 23, 2001 Wall Street Journal article concerning the JAMA article and a September 25, 2001 Associated Press piece reporting on the FDA Warning Letter.

D. Withdrawal of VIOXX from the Market

In September 2004, Merck was in the process of conducting another study of VIOXX to assess the effects of continuous treatment with VIOXX on the prevention and growth of recurrent colon polyps (known as the "APPROVe" study). An External Safety Monitoring Board ("ESMB") established to oversee APPROVe observed an increased rate of thrombotic events for patients taking VIOXX compared with patients taking a placebo and informed Merck that it was recommending that the study be stopped. On September 30, 2004, Merck voluntarily withdrew VIOXX from the market.

stating that its decision was based on the data observed by the ESMB overseeing the APPROVe study and the availability of alternative therapies. (Id., Ex. 21, at 1.)

E. VIOXX Securities Fraud Litigation

On November 6, 2003, Plaintiffs filed the first VIOXX-related securities class action against Merck in the United States District Court for the Eastern District of Louisiana (the "Pringle action"). The Complaint alleged that Merck's failure to disclose material information about the cardiovascular risks of VIOXX had inflated the price of Merck stock and that plaintiff investors sustained a loss when the truth was revealed in October 2003, causing the stock price to decline. The Second Amended Complaint, filed on August 9, 2004, named Dr. Scolnick as a Defendant. Numerous additional suits were filed, in particular after Merck's withdrawal of VIOXX from the market. On February 23, 2005, the Judicial Panel on Multidistrict Litigation transferred all securities, shareholder derivative and ERISA actions relating to VIOXX to this Court.

The Complaint in the instant multi-districted securities class action contains six counts, asserting various claims under the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. 78a, et seq., (2000), and the Securities Act of 1933 ("Securities Act"), 15 U.S.C. 77a, et seq., (2000). Lead Plaintiffs Richard Reynolds, Steven LeVan, Jerome Haber and the Public Employees' Retirement System of Mississippi represent a class of plaintiffs consisting of the purchasers of Merck securities between May 21, 1999 and October 29, 2004. They claim that Merck

made misrepresentations and omissions of material fact with respect to Vioxx's safety and cardiovascular risks, which deceived the investing public, artificially inflated the market price of Merck securities and caused the Class to purchase Merck securities at artificially inflated prices. Plaintiffs Rhoda Kanter and Park East, Inc. purchased shares of Merck common stock through the Merck Stock Investment Plan ("MSIP") pursuant to Merck's April 26, 2002 Registration Statement and April 30, 2002 Prospectus. Kanter and Park East assert Securities Act claims on behalf of class members who purchased Merck stock through the MSIP.

Defendants move to dismiss the Complaint in its entirety with prejudice under Federal Rule of Civil Procedure 12(b)(6) and the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4, et seq., (2000).

II. LEGAL STANDARDS

A. Standard of Review

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, the plaintiff is not entitled to relief. Oran v. Stafford, 226 F.3d 275, 279 (3d Cir. 2000). In other words, relief under Rule 12(b)(6) is warranted if it appears beyond doubt that no relief could be granted "under any set of facts which could prove consistent with the allegations." Hishon v. King & Spalding, 467 U.S. 69, 73 (1984); Zynn v. O'Donnell, 688 F.2d 940, 941 (3d Cir. 1982). In evaluating a Rule 12(b)(6)

motion to dismiss for failure to state a claim, a court may consider only the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if the complainant's claims are based upon those documents. See Pension Benefit Guar. Corp. v. White Consol. Indus., 998 F.2d 1192, 1196 (3d Cir. 1993).

The issue before the Court "is not whether plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence in support of the claims." Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1420 (3d Cir. 1997) (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974)). In this case, Defendants have moved under Rule 12(b)(6), in part on the grounds that Plaintiffs' claims are barred by the applicable statutes of limitations. To dismiss claims based on a statute of limitations defense, the time bar must be apparent on the face of the Complaint. Bethel v. Jendoco Contsr. Corp., 570 F.2d 1168, 1174 (3d Cir. 1978). Thus, Plaintiffs will not be entitled to pursue their claims if those claims are facially untimely.

B. Applicable Statutes of Limitations

Counts One through Three of the Complaint allege violations of sections 10(b), 20(a) and 20A of the Exchange Act, and Rule 10b-5 promulgated thereunder. 15 U.S.C. §§ 78j(b), 78t(a), 78t-1. Because this action was filed on November 6, 2003, after the enactment of the Sarbanes-Oxley Act on July 30, 2002, the limitations period set by Sarbanes-Oxley applies to Plaintiffs' Exchange Act claims. Lieberman v. Cambridge Partners, L.L.C., 432 F.3d 482, 489 (3d Cir. 2005). Sarbanes-Oxley extended the

limitations period for private securities fraud claims under the Exchange Act to the earlier of two years after the discovery of the facts constituting the violation or five years after the violation. 28 U.S.C. § 1658(b). Prior to Sarbanes-Oxley, the applicable limitations periods were one and three years, respectively. 15 U.S.C. § 78i(e). While other circuits have held that Sarbanes-Oxley does not revive claims that were otherwise time-barred as of July 30, 2002, when the statute went into effect, see, e.g., In re ADC Telecomm., Inc. Sec. Litig., 409 F.3d 974 978 (8th Cir. 2005), the Court notes that Defendants have not argued that Plaintiffs' claims had expired by that date. The parties do not dispute that the applicable limitations period is the two-year/five-year structure under Sarbanes-Oxley.

The remaining three Counts of the Complaint assert violations of sections 11, 12(a)(2) and 15 of the Securities Act. 15 U.S.C. §§ 77k, 77l(a)(2), 77o. Section 13 of the Securities Act provides the applicable statute of limitations. It states in relevant part:

> No action shall be maintained to enforce any liability created under section 77k [section 11] or 77l(a)(2) [section 12(a)(2)] of this title unless brought within **one year** after the discovery of the untrue statement or the omission, or after such discovery should have been made by the exercise of reasonable diligence.

15 U.S.C. § 77m (emphasis added). Although the statute refers only to causes of action under sections 11 and 12(a)(2), the Complaint's control person claim

under section 15 is also governed by the one-year limitations period. Benak v. Alliance Capital Mgmt., L.P., 349 F.Supp.2d 882, 887 n.6 (D.N.J. 2004), aff'd, 435 F.3d 396 (3d Cir. 2006) (citing Hill v. Equitable Bank, Nat'l Assn., 599 F.Supp. 1062, 1078 (D. Del. 1984)).

C. Accrual of Claims: Third Circuit's "Inquiry Notice" Standard

Third Circuit jurisprudence requires this Court to apply an "inquiry notice" standard in determining when Plaintiffs' securities fraud claims accrued. Benak v. Alliance Capital Mgmt., L.P., 435 F.3d 396, 400 (3d Cir. 2006); In re NAHC, 306 F.3d 1314, 1325 (3d Cir. 2002). Under this standard, plaintiffs need not have actual knowledge or know all of the details of the alleged fraud to trigger the limitations period. NAHC, 306 F.3d at 1325-26. Rather, inquiry notice exists when the plaintiffs discovered, or in the exercise of reasonable diligence should have discovered the general fraudulent scheme. Id. at 1326. It is at that point that the clock starts to run on the limitations period. Id.

The inquiry notice analysis is an objective one. The Court must evaluate whether sufficient information of wrongdoing or "storm warnings" of culpable activity existed such that a "reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning." Id. at 1325 (quoting Matthews v. Kidder, Peabody & Co., Inc., 260 F.3d 239, 252 (3d Cir. 2001)). Storm warnings may include "any financial, legal or other data that would alert a reasonable person to the probability that misleading

statements or significant omissions had been made." Id. at 1326, n. 5 (quoting Matthews, 260 F.3d at 252). Once storm warnings give rise to inquiry notice and trigger the limitations period, plaintiffs have an obligation to investigate the basis for their claims. Id. at 1326. The Court must charge them with constructive knowledge of all information discoverable through diligent research during that period. Id.

If a defendant succeeds in establishing inquiry notice, the burden then shifts to the plaintiffs to demonstrate that they were unable to discover their injuries despite the exercise of reasonable due diligence. Benak, 435 F.3d at 400. In other words, the plaintiffs must show that they undertook their duty to investigate the basis for their claims but nevertheless failed to discover information necessary to initiate a securities fraud action. Choosing not to investigate, however, is not a viable option, even in spite of protestations by plaintiffs that any efforts to acquire relevant information would have been difficult or fruitless. Id. at 401. "[I]f storm warnings existed, and the plaintiffs choose not to investigate, we will deem them on inquiry notice of their claims." Id. (quoting Matthews, 260 F.3d at 252 n. 16.)

III. ANALYSIS

A. Exchange Act Claims

Plaintiffs filed the initial securities fraud class action complaint in the Pringle action on November 6, 2003. Under the two-year limitations period applicable to their Exchange Act claims, Plaintiffs would have to have been on notice of their claims no

earlier than November 6, 2001 for the claims to surmount the limitations bar. The evidence properly before the Court on this Rule 12(b)(6) motion - meaning the news articles, analyst reports, public documents and material referenced in the Complaint - demonstrates that Plaintiffs were on inquiry notice of their claims against Merck and Dr. Scolnick no later than October 9, 2001. On this date, the New York Times ran an article in which Dr. Scolnick acknowledged that Merck knew that the cardioprotective effect of naproxen was not proven and, further, that Merck admitted that VIOXX may raise the risk of heart attack or other thrombotic event. Moreover, by October 9, 2001, an overwhelming collection of information signaling deceit by Merck with respect to the safety of VIOXX had accumulated in the public realm.

On September 21, 2001, the FDA published its Warning Letter of September 17, 2001 to Merck on its website.[2] The language of the Warning Letter is explicit. It charges Merck with engaging in deceptive and misleading conduct with regard to the safety profile of VIOXX. In particular, and in no uncertain terms, the FDA accuses Merck of misrepresentation by endorsing the naproxen hypothesis as fact, despite knowing that the cardioprotective effect of naproxen was merely hypothetical and unsupported by evidence. In addition, it publicly reprimands

[2] In addition to the fact that the September 17, 2001 FDA Warning Letter is a matter of public information, it is also properly considered by this Court on this motion to dismiss because it is specifically referenced in the Complaint. Burlington Coat Factory, 114 F.3d at 1426.

Merck for downplaying the potential safety problems with the drug by failing to disclose the known possibility that Vioxx increases the risk of myocardial infarction. The Warning Letter specifically references the VIGOR study and expresses the FDA's censure of the manner in which Merck has characterized the results of the study in its promotional activities and other public disclosures. Moreover, the accusations in the Warning Letter have particularly strong impact in light of the fact that they are leveled by Merck's principal regulator, which not only identifies specific improper conduct by Merck but also requires Merck to propose an action plan that would include ceasing misleading promotional activities and disseminating corrective messages.

A reasonable investor in Merck would have discovered this public, company-specific information and recognized it as a storm warning of fraud. Benak, 435 F.3d at 400-02 (discussing soundness of assumption in inquiry notice analysis that a direct investor in a company has motivation to stay informed about investment and would recognize information about company troubles as storm warning). The Warning Letter accused Merck of presenting as fact information that it knew was not. The wrongdoing charged in the Warning Letter is, moreover, the same alleged misconduct on which the securities fraud claims in this case are predicated. Indeed, the Court might arguably conclude that the FDA Warning Letter alone excited storm warnings sufficient to put Plaintiffs on inquiry notice of their claims against Merck.

The Court, however, need not make that conclusion, because the FDA Warning Letter was not issued in a vacuum of information. In fact, for months leading up to the issuance of the September 17, 2001 Warning Letter, numerous articles - many published in such mainstream news publications as The New York Times and USA Today - reported on the competing prothrombotic hypothesis to explain the VIGOR study results and the possibility that VIOXX in fact increased the risk of heart attack.[3] The media echoed doubts about the safety of Merck's blockbuster drug. The August 22, 2001 JAMA article warned that data obtained from a VIOXX study indicated that its use "might lead to increased cardiovascular events." The JAMA article received

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[3] Some of the articles considered by the Court herein in its inquiry notice analysis are referenced in the Complaint, such as the August 2001 JAMA article, while others are not. The Court may take judicial notice of public material such as newspaper articles and analyst reports and consider them in applying the inquiry notice standard, even though the materials are extraneous to the Complaint. Benak, 435 F.3d at 400-01. In so holding, the Third Circuit reasoned as follows:

> The inquiry notice analysis is an objective one. Whether appellants read the articles or were aware of them is immaterial. They serve only to indicate what was in the public realm at the time, not whether the contents of those articles were in fact true. "The Court may take judicial notice of newspaper articles for the fact of their publication without transforming the motion into one for summary judgment."

Id. at 401 n. 15 (quoting In re Merrill Lynch & Co. Research Reports Sec. Litig., 289 F.Supp.2d 116, 125 n. 15 (S.D.N.Y. 2003)) (citations omitted).

press coverage and attention from financial analysts. Clearly, information raising at the very least doubts as to the safety profile of VIOXX accumulated in the public realm prior to the issuance of the Warning Letter. Moreover, a class action product liability suit was filed against Merck in the spring of 2001. The complaint in that case alleged that VIOXX was not safe, that patients taking the medication were subject to an increased risk of suffering a heart attack and that Merck's research bore this out. While not conclusive of knowing misrepresentations or omissions by Merck with regard to VIOXX, the product liability litigation must be recognized as a sign of the brewing storm. See Benak, 435 F.3d at 403 n. 20 (finding that the filing of a related lawsuit was a public event contributing to the existence of inquiry notice); see also In re Initial Public Offering Sec. Litig., 341 F.Supp.2d 328, 349 (S.D.N.Y. 2004) ("The filing of related lawsuits can suffice to put plaintiffs on inquiry notice, where the alleged fraud is similar").

Public discussion of possible troubles at Merck continued, and it be may even be said intensified immediately following the publication of the Warning Letter. No fewer than eleven articles were published by such mainstream news services as Reuters, USA Today, The Wall Street Journal, The New York Times and The Associated Press between September 24, 2001 and October 9, 2001. The theme was consistent: the FDA "[has] charged drug giant Merck and Co., Inc. with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks." (Baron Decl., Ex. 123.)

The last in this series of articles cited by Defendants - the October 9, 2001 New York Times article - presents a particularly probative indication of actionable misrepresentations by Merck concerning VIOXX. The article quotes defendant Dr. Scolnick - who was then president of Merck's research laboratories - as saying with regard to the VIGOR study results: "There are two possible interpretations. Naproxen lowers the heart attack rate, or Vioxx raises it." (Rolnick Cert., Ex. A.) Dr. Scolnick's statement admitted that Merck recognized the possibility that VIOXX may increase a user's risk of heart attack. It therefore represents a significant departure from Merck's company line as to the explanation for the VIGOR study results.

Add to this body of information readily available in the days and weeks after the FDA issued its Warning Letter the initiation of lawsuits related to VIOXX's alleged propensity for increasing a patent's risk of heart attack. The suits filed in New Jersey and Utah in late September 2001 are significant for two reasons. One, although they plead for relief under different legal theories than those at issue here - namely, under products liability and consumer fraud causes of action rather than securities fraud - the lawsuits are predicated upon the same alleged wrongdoing as the allegations on which Plaintiffs base their securities fraud claims. The suits revolve around Merck's alleged misrepresentations and omissions regarding the known possibility that Vioxx increased a patient's risk of a thrombotic event. Two, the class action complaint in Astin, the New Jersey consumer fraud class action, and the 16-plaintiff complaint in the Utah state court action rely on such

publicly available information as the JAMA article, the FDA Warning Letter and news stories reported by the Associated Press and the Wall Street Journal. The fact that the information available by the end of September 2001 would give those plaintiffs sufficient notice to file statutory and common law fraud claims as well as failure to warn claims against Merck reinforces the Court's conclusion that a reasonable investor of ordinary intelligence would have recognized, no later than early October 2001, warnings of troubles at Merck bearing on his or her investments.

The Court is not persuaded otherwise by Plaintiffs' argument that positive information about VIOXX disseminated by Merck in the months both before and after the publication of the FDA Warning Letter counterbalanced and offset any storm warnings. While the law of this Circuit does recognize that reassurances given by a company can dissipate storm warnings, an investor may not reasonably rely on words of comfort from management "when there are direct contradictions between the defendants' representations and the other materials available to plaintiffs regarding the possibility of fraud." In re Exxon Mobil Corp. Sec. Litig., 387 F.Supp.2d 407, 418 (D.N.J. 2005); see also Benak, 435 F.3d at 402 n. 16 ("Reassurances can dissipate apparent storm warnings 'if an investor of ordinary intelligence would reasonably rely on them to allay the investor's concerns'") (quoting Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 169 (2d Cir. 2005)). While the mix of information prior to September 2001 included both negative information about possible safety problems with VIOXX, as well

as the company's positive reassurances about the product and news and analyst reports echoing this off-setting information, the company reassurances ceased to be reliable upon the publication of the FDA Warning Letter. As discussed, the Warning Letter expressly charged Merck with misrepresenting the safety profile of VIOXX, misleading the public by presenting the naproxen hypothesis as the reason for the increased incidence of heart attacks in patients taking VIOXX in the VIGOR study and failing to disclose that the results may also be due to pro-thrombotic properties of VIOXX. A reasonable investor could not continue to rely on Merck's reassurances to allay his or her concerns in light of this public information.

Plaintiffs have tried to minimize the impact of the Warning Letter by arguing that their claims center on the contention that Merck, at the time it touted the naproxen hypothesis, actually knew that VIOXX increased the risk of heart attack. Plaintiffs, in fact, sought permission to submit supplementary briefing on the relative unimportance of the Warning Letter and the other lawsuits to the storm warning analysis. While the Court has read the untimely submission, it notes that the letter brief merely amplifies the argument raised at oral argument. To summarize, in Plaintiffs' view, public information such as the FDA Warning Letter, which castigated Merck for its misrepresentation of the safety profile of VIOXX by promoting the naproxen hypothesis without evidence to support it, did not put Plaintiffs on notice that Merck's fraud was more extensive, viz. actively promoting the naproxen hypothesis while knowing it was false. Plaintiffs thus argue that they

did not have inquiry notice of Defendants' "true" more extensive fraud until, at the earliest, Merck revealed information in October 2003 that the commercial performance and even viability of VIOXX were in jeopardy.

This argument is untenable. As noted earlier, inquiry notice exists when Plaintiffs discovered, or in the exercise of reasonable diligence should have discovered the general fraudulent scheme. NAHC, 306 F.3d at 1326. They need not have discovered every detail of the alleged fraud, nor need they have a thoroughly developed lawsuit ready to file at the moment at which inquiry notice arises. Id. at 1327. Plaintiffs' position that their claims did not accrue until the existence of fraud was a probability, as opposed to a possiblity, and that the "facts that give rise to inquiry notice must be sufficiently advanced and substantiated to enable the plaintiff to 'tie up any loose ends' before filing suit" (Pl. Br. at 58) is simply not supported by Third Circuit law. Their argument that fraudulent statements made after November 6, 2001 delay the running of the limitations period is likewise incorrect. This Court is not aware of any authority, nor has any been cited by Plaintiffs, in support of the contention that inquiry notice of fraud does not exist until corrective disclosures are made.

Here, by November 6, 2001, Plaintiffs were already on notice that the FDA had accused Merck of misrepresenting the safety profile of VIOXX by promoting a theory that had not been demonstrated by substantial evidence. In the Warning Letter, the FDA admonishes Merck by stating:

> You assert that Vioxx does not increase the risk of MIs and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have prothrombotic properties.

The FDA focuses its criticism of Merck on Merck's knowing misrepresentation of Vioxx's safety profile:

> Your misrepresentation of the safety profile for Vioxx is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for Vioxx that also misrepresented Vioxx's safety profile.

Surely, this charge by the FDA against Merck, of making factual claims while knowing it does not have factual support for them, is not merely a "red flag" suggesting fraud. Rather, it is a direct and unequivocal accusation of fraud. Plaintiffs premise this lawsuit on Defendants' alleged knowing misrepresentation of the safety profile of VIOXX, that is, on the allegation that Merck promoted VIOXX as having a safety profile superior to traditional NSAIDs even though, according to Plaintiffs, it knew that VIOXX increased a user's risk of heart attack. It is prepostorous for Plaintiffs to argue that because they did not have a "smoking gun" that demonstrated that Defendants' misrepresentation was even more egregious than the

Warning Letter charged, they were not on inquiry notice of a general fraudulent scheme regarding the safety of VIOXX.

Publication of the Warning Letter added to the available mix of information in a significant way, as there can be no doubt that in possession of this body of knowledge - including the press coverage which immediately followed - a reasonable investor of ordinary intelligence would identify the possibility that Merck had knowingly misrepresented material facts with regard to VIOXX. Indeed, the torrent of publicity discussed above is more akin to thunder, lightning and pouring rain than subtle warnings of a coming storm. Read in light of the accumulation of public information about Merck's misrepresentation of the safety profile of VIOXX, the New York Times article of October 9, 2001 leaves no doubt that by then, investors in Merck securities knew or should have known of the general fraudulent scheme perpetrated by Merck with regard to the safety of VIOXX. The article marks October 9, 2001 as the latest possible date on which Plaintiffs can be charged with inquiry notice of their fraud claims against Merck and Dr. Scolnick.

The reasoning and holding of the Third Circuit in Benak v. Alliance Capital Management compel this conclusion. Benak was a private securities fraud action brought not by a direct investor in a company against the company, but by mutual fund investors against the mutual fund and its advisers. One of the companies in which the subject fund invested its clients' money was Enron. The plaintiff investors asserted securities fraud claims, alleging that the fund's publicized claims of its investment strategies

and companies in which it invested were materially misleading in light of the fund's continued investment in Enron despite the negative public information about Enron's financial state. Benak, 435 F.3d at 398-99. On the defendants' motion, the district court dismissed the Benak class action complaint on statute of limitations grounds. Applying the inquiry notice principles it articulated in NAHC, the Third Circuit Court of Appeals affirmed the dismissal. Id. at 404.

Of particular relevance to this case is the Benak court's acknowledgment of the difference between a direct investor and a mutual fund investor. In particular, for the purposes of the inquiry notice analysis, the Court observed that whereas an investor who invests directly in a company would be charged with keeping abreast of information about the company, including its performance and possible troubles, a mutual fund investor stands in a disadvantaged position in terms of identifying information probative of problems affecting his or her investments. Id. at 402-03. The reason for the disadvantage is two-fold. First, a fund investor reasonably passes the responsibility for maintaining consistent knowledge of the condition of different companies on to the fund. Id. at 402. Second, a fund investor may have little idea at any one time in what securities his or her money is invested. Id. Contrasting the treatment of a direct investor and a mutual fund investor in the inquiry notice analysis, the Court reasoned as follows:

> Undergirding the inquiry notice analysis is the assumption that a plaintiff either was or should have been able, in the exercise of

> reasonable diligence, to file an adequately pled securities fraud complaint as of an earlier date. In the case of a direct investor - who one would assume has or can be deemed to have consistent knowledge of his or her securities holdings - the storm warning analysis becomes relatively simple. Upon reading news reports regarding the financial woes of a particular company and speculation regarding the management of that company, a direct investor immediately has reason for concern. Moreover, in being responsible for his or her own investments, a direct investor has greater motivation - and therefore, one would assume, be more likely - to stay informed. Upon receiving such information and inquiring further regarding the accuracy of that information, a direct investor - again, knowing the amount and nature of his or her holdings - could file suit almost immediately.

Id. at 401.

In short, in tweaking the inquiry notice analysis to fit the peculiarities of a mutual fund investor's potential securities fraud claims, the Third Circuit in Benak instructed that storm warnings as to a direct investor's fraud claims will arise upon a much lower threshold of information than storm warnings surrounding a mutual fund investor's stake in a company. The Benak court then went on to conclude that, even upon the higher threshold of information required to put the mutual fund investor on inquiry notice, the standard had been met as to the Benak plaintiffs based on news articles about possible

troubles at Enron, combined with the publicity given to Enron's bankruptcy filing, media accounts noting the mutual fund's holdings in Enron, and the earlier filing of a lawsuit predicated on related wrongdoing. Id. at 403. Because these storm warnings existed well before one year before the complaint was filed,[4] the Third Circuit concluded that the District Court had properly dismissed the complaint as time-barred.

In this case, of course, the Court deals with claims brought by direct investors in Merck. For the reasons discussed above, the abundant public information leading up to and immediately following the FDA Warning Letter - in addition to the Warning Letter itself - would give an investor in Merck reason for concern and charge him or her with the responsibility of conducting a diligent investigation. The latest accrual date that would permit the Court to conclude that Plaintiffs' Exchange Act claims are not precluded by the statute of limitations is November 6, 2001. Given that the FDA Warning Letter was published on September 21, 2001, and that it received a substantial amount of attention from the media and financial analysts immediately following its publication, the Court finds that it is clear that storm warnings of fraud by the company existed more than two years before this Complaint was filed.

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[4] The pre-Sarbanes-Oxley one-year statute of limitations under 15 U.S.C. § 78i(e) applied to the claims in Benak. Benak, 435 F.3d at 400.

Once the burden has been met by the defendants to demonstrate storm warnings, the burden shifts to the plaintiffs to show that they exercised reasonable due diligence but nevertheless were unable to discover their injuries. Plaintiffs here have not argued that they conducted a diligent investigation, and nothing in the Complaint demonstrates that they were unable to uncover pertinent information during the limitations period. Thus, "the knowledge they would have inquired through investigation is imputed to them." Benak, at 401. For the reasons discussed above, a reasonable investor would have discovered the basis for his fraud claims against Merck with respect to alleged misrepresentations about VIOXX within the two years following the storm warnings which existed before November 6, 2001.

Because the instant securities fraud action was filed over two years from the time that Plaintiffs were on inquiry notice of their claims, the Complaint's Exchange Act claims are barred by the applicable statute of limitations. Defendants' motion to dismiss must be granted, as Plaintiffs have failed to state a cause of action upon which this Court may order relief.

B. Securities Act Claims

Having concluded that Plaintiffs were on inquiry notice of their claims by early October 2001, the Court finds that Plaintiffs' Securities Act claims are also time-barred. The claims brought under the Securities Act relate to stock purchased through the MSIP pursuant to Merck's April 26, 2002 Registration Statement and April 30, 2002

Prospectus. It follows from the analysis in Section III.A of this Opinion that Plaintiffs were on inquiry notice of their Securities Act claims based on the allegedly false representations made in the April 2002 Registration Statement and Prospectus immediately upon the issuance of these documents. Under the one-year statute of limitations applicable to Securities Act claims, these claims expired no later than April 30, 2003, months before this lawsuit was filed. Accordingly, Counts Three through Six of the Complaint must also be dismissed as time-barred.

IV. Conclusion

For the foregoing reasons, the Court grants Defendants' motions to dismiss. The entire Complaint must be dismissed with prejudice as untimely. An appropriate form of Order will be filed.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge

Dated: April 12, 2007

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Nos. 07-2431, 07-2432

IN RE: MERCK & CO., INC. SECURITIES, DERIVATIVE & "ERISA" LITIGATION
(MDL No. 1658)

CONSOLIDATED SECURITIES LITIGATION

Richard Reynolds, Steven LeVan, Jerome Haber and The Public Employees' Retirement System of Mississippi, the Court-Appointed Lead Plaintiffs and Plaintiffs Union Asset Management Holding AG, Loren Arnoff, Robert Edwin Burns, Jan Charles Finance S.A., Martin Mason, Frank H. Saccone, Charlotte Savarese, Joe Savarese, Joseph Goldman, Sherrie B. Knuth, Joseph S. Fisher, M.D., Naomi Raphael, Rhoda Kanter, Park East, Inc. and Marc Nathanson, on behalf of themselves and the proposed class of purchasers of Merck securities during the period between May 21, 1999 and October 29, 2004,

Appellants

SUR PETITION FOR REHEARING

Present: SCIRICA, Chief Judge, SLOVITER, RENDELL, BARRY, AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN, and ROTH,* Circuit Judges

* Hon. Jane R. Roth, Senior Circuit Judge, as to panel rehearing only.

The petition for rehearing filed by Appellees In Re: Merck & Co., Inc., in the above-entitled case having been submitted to the judges who participated in the decision of this court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court en banc, the petition for rehearing is denied. Judge Roth would grant panel rehearing, Judge Rendell, Judge Ambro, Judge Fuentes, and Judge Jordan would grant rehearing en banc.

By the Court,

/s/ Dolores K. Sloviter
Circuit Judge

Dated: October 17, 2008
CMD/cc: All Counsel of Record

OPPOSITION BRIEF

Supreme Court, U.S.
FILED
MAR 23 2009
OFFICE OF THE CLERK

No. 08-905

IN THE
Supreme Court of the United States

MERCK & CO., INC., ET AL.,
Petitioners,

v.

RICHARD REYNOLDS, ET AL.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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QUESTION PRESENTED

Did the Third Circuit err in holding – in accordance with the law of every circuit – that a plaintiff is not on inquiry notice of securities fraud until it receives "storm warnings" of that fraud and in determining that, under the particular facts of this case, no storm warnings existed?

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INTRODUCTION

The Third Circuit correctly held, based on a detailed factual analysis of Respondents'[1] Complaint,[2] that the statute of limitations had not expired when Respondents filed this securities fraud lawsuit.[3] In so doing, the Third Circuit applied a test that has been endorsed by every Court of Appeals to consider the issue. The circuits uniformly hold that a plaintiff is not on "inquiry notice" until there are sufficient facts available to the plaintiff – "storm warnings" – that would arouse suspicions of the alleged fraud in a reasonable investor. Only after concluding that this first prong of the statute of limitations test is satisfied – *i.e.*, sufficiently suspicious facts exist to trigger a duty to investigate – do courts consider the second prong, namely, whether the plaintiff conducted a reasonable investigation and whether such investigation would have uncovered enough information to bring suit. This case involves only the uncontroverted first prong of this analysis: the "storm warnings" prong.

The Third Circuit concluded that no storm warnings of the alleged fraud existed more than two years prior to the filing of the original complaint. The court's holding did not articulate a new or different standard for determining the existence of storm warnings. Rather, the decision resulted from a fact-bound analysis of the securities fraud alleged in

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[1] Respondents include Co-Lead Plaintiffs in the securities fraud action currently before the District Court.

[2] Corrected Consolidated and Fourth Amended Class Action Complaint (filed June 14, 2005) ("Compl.").

[3] The Complaint also asserts non-fraud claims under §§ 11, 12(a)(2), and 15 of the Securities Act of 1933, 15 U.S.C. §§ 77k, 77*l*(a)(2), 77*o*.

Respondents' Complaint and whether publicly available information would have aroused suspicion of that fraud. As the Third Circuit recognized, the gravamen of the Complaint was that Petitioners believed that Merck's drug VIOXX ("Vioxx") was to blame for the results of a large-scale clinical trial – which showed that significantly more patients taking Vioxx suffered adverse cardiovascular events, particularly heart attacks, than patients who took the comparator drug, naproxen – but misled investors by proffering an opinion that these results were likely attributable to an alleged cardio-protective effect of naproxen rather than a harmful effect of Vioxx (the so-called "naproxen hypothesis"). The Third Circuit recognized that, as of November 6, 2001 (two years before the filing of the initial complaint), there were no storm warnings that Petitioners did not believe their naproxen hypothesis.

Because the court found no storm warnings, it had no need to (and did not) address the second prong of the statute of limitations test: whether, once Respondents received storm warnings, a reasonably diligent investigation would have yielded sufficient details of the fraud to file a complaint. As Petitioners themselves recognize, the purported circuit split they identify relates to that *second* prong of the test – *i.e.*, whether and when, *after* the plaintiff is under a duty to investigate, the statute of limitations is triggered. *See* Pet. 3. To the extent any such differences among the circuits on the second prong of the test produce different outcomes, those decisions have no application here. Absent storm warnings, Respondents had no duty to investigate in the first place. Petitioners may disagree with the Third Circuit's fact-bound conclusion that there were no storm

warnings that Petitioners did not actually believe their publicly proffered naproxen hypothesis, but they cannot trace their disagreement to the Third Circuit's articulation of the first prong of the test, which is consistent with that of every other circuit.

Thus, this case does not implicate any circuit split or warrant further review. The disagreement between the District Court and the Third Circuit turned not on the applicable law but on how, as a factual matter, to characterize Respondents' claims. The District Court, prompted by Petitioners, mistakenly characterized Respondents' claims as alleging that Merck misrepresented the "fact" that the naproxen hypothesis was unproven.[4] Proceeding from this fundamental misunderstanding of Respondents' allegations, the District Court held that there were storm warnings that the naproxen hypothesis was unproven. The Third Circuit correctly recognized that the Complaint did not allege such a fraud; rather, the Complaint alleged that Petitioners misled investors by proffering an opinion on medical research results that they did not honestly hold. Such highly fact-bound questions concerning the nature of the fraud alleged and whether storm warnings of that fraud existed do not warrant this Court's review.

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[4] Petitioners' argument to this Court is premised on the same mischaracterization of the gravamen of Respondents' claims.

STATEMENT

A. Statutory and Doctrinal Background.

Section 10(b) of the Securities Exchange Act of 1934 ("1934 Act") provides that "[i]t shall be unlawful for any person ... [t]o use or employ, in connection with the purchase or sale of any security ..., any manipulative or deceptive device or contrivance." 15 U.S.C. § 78j(b). A private right of action "ha[s] been implied under th[is] statute for nearly half a century." *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350, 358 (1991). While most securities fraud claims are predicated on factual misstatements, "statements of reasons, opinion, or belief" may also form the basis of a claim, if the speaker "did not hold the beliefs or opinions expressed." *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1090 (1991); *see id.* at 1090-96.

In *Lampf*, this Court held that a one-year statute of limitations governed the private right of action under § 10(b), requiring plaintiffs to bring claims "within one year after the discovery of the facts constituting the violation." 501 U.S. at 359-60, 364 (based on limitations period for similar 1934 Act causes of action). Subsequently, Congress codified a two-year statute of limitations for private securities fraud claims. 28 U.S.C. § 1658(b) ("a private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement ... may be brought not later than the earlier of ... 2 years after the discovery of the facts constituting the violation").

The circuits agree that the statute of limitations is triggered when the plaintiff has either actually or constructively discovered the "facts constituting the

violation." The circuits also agree that the appropriate question for determining whether a plaintiff is on inquiry notice is to ask whether the plaintiff received sufficient "storm warnings" of the alleged fraud such that a reasonable investor would have investigated further. All circuits agree that, if a plaintiff received no such "storm warnings," the statute of limitations does not begin to run. *See* pp. 14-16, *infra*.

B. Nature of the Action.

1. Respondents' Complaint.

On November 6, 2003, the initial securities fraud class action complaint was filed. On February 23, 2005, the Judicial Panel on Multidistrict Litigation transferred the various Vioxx-related securities actions to the District Court in New Jersey, where they were consolidated. On June 14, 2005, Respondents filed the Complaint at issue on this appeal.

The gravamen of Respondents' Complaint was that Merck and its senior officers – Petitioners here – made false statements of opinion by asserting that they believed that the results of the large-scale Vioxx Gastrointestinal Outcomes Research clinical trial ("VIGOR") were attributable to alleged cardioprotective properties of naproxen, when in fact they believed that these results were attributable to Vioxx's harmful cardiovascular effects. *See* Pet. App. 35a. As the Complaint alleged:

In May 1999, the Food and Drug Administration ("FDA") approved Vioxx, a new drug developed by Merck. Vioxx is a nonsteroidal anti-inflammatory drug ("NSAID") used in the treatment of pain from arthritis and other ailments. Traditional NSAIDs, such as aspirin, ibuprofen, and naproxen, function by inhibiting two enzymes: one which helps maintain

the stomach's protective lining and one which is associated with pain and inflammation. In contrast, Vioxx suppresses only the latter enzyme, and therefore was believed to significantly reduce the harmful gastrointestinal side effects associated with long-term use of other NSAIDs. *See id.* at 5a.

Merck vigorously touted Vioxx as possessing the pain-suppressing benefits of traditional NSAIDs, but without the harmful gastrointestinal side effects. The market, in turn, viewed Vioxx as a potential "blockbuster" and "savior" for Merck. *See id.*

Well before introducing Vioxx to the market, however, Merck had serious concerns that Vioxx caused harmful cardiovascular events, including heart attacks. In internal emails from 1997, which were not publicly disclosed until November 2004, top Merck scientists stated that the "possibility of increased [cardiovascular] events is of great concern" (Compl. ¶ 88) and could "kill [the] drug" (Pet. App. 6a) (alteration in original).

In January 1999, Merck commenced the VIGOR trial, which compared Vioxx to naproxen, the active ingredient in brand-name pain relievers such as Aleve. The purpose of VIGOR was to demonstrate that Vioxx caused fewer gastrointestinal problems than traditional NSAIDs and to thereby allow Merck to seek a more favorable drug label for Vioxx from the FDA. VIGOR produced mixed results for Merck: Vioxx users suffered significantly fewer gastrointestinal problems than naproxen users but significantly more adverse cardiovascular events, particularly heart attacks. *See id.*

Reviewing those data, Merck internally concluded that Vioxx caused the higher rates of adverse cardio-

vascular events suffered by Vioxx users. Indeed, in a March 9, 2000 internal email, a senior Merck officer who was also the Company's top scientist responsible for the development of Vioxx wrote that the cardiovascular events among Vioxx users in the VIGOR trial "are clearly there" and that "it is mechanism based as we worried it was." Compl. ¶ 136; *see* Pet. App. 6a.

Despite having internally reached this conclusion, when Merck announced the VIGOR results to the market, it opined that the difference in rates of adverse cardiovascular events was likely the result of alleged cardio-protective properties of naproxen rather than a harmful effect of Vioxx (the "naproxen hypothesis"). For example, as Merck stated on March 27, 2000:

> [S]ignificantly fewer [cardiovascular] events were observed in patients taking naproxen in this [gastrointestinal] outcomes study, *which is consistent with naproxen's ability to block platelet aggregation*. This effect on these events had not been observed previously in any clinical studies for naproxen. *Vioxx ... does not block platelet aggregation and therefore would not be expected to have similar effects.*

Id. at 7a (emphases added).

The VIGOR results were widely reported in the press, medical journals, and securities analyst reports. Market analysts, scientists, and the press immediately understood that there were two possible explanations for the VIGOR results: either Vioxx caused heart attacks or naproxen prevented them. Although Merck acknowledged that its naproxen hy-

pothesis was unproven and that no large-scale clinical trials had tested whether naproxen was cardioprotective, virtually all in the scientific and financial communities accepted Merck's naproxen hypothesis as the most likely explanation for the higher incidence of adverse cardiovascular events observed among Vioxx users in VIGOR. *See id.* at 8a.

Petitioners repeatedly assured the market of their belief in the naproxen hypothesis and that Vioxx was "safe." *See id.* at 45a-46a. Petitioners also projected that Vioxx, Merck's second-best selling drug, would continue to generate "blockbuster" revenues for the company. *See id.* at 5a. Many securities analysts echoed this sentiment and gave Merck their highest "buy" rating. *See id.* at 14a. Thus, the Complaint alleges that Merck's stock price remained higher than it would have been had the market known the truth: that Petitioners *actually* believed that Vioxx caused heart attacks.

On October 30, 2003, *The Wall Street Journal* reported that a large-scale study by Brigham and Women's Hospital found that Vioxx users had increased heart attack risk compared to patients taking Celebrex (a competitor drug that, like Vioxx, suppressed only the enzyme associated with pain and inflammation). *See id.* at 18a. Despite having sponsored this study, Merck criticized its findings.

On September 30, 2004, Merck withdrew Vioxx from the market after another study showed "an increased risk of confirmed [cardiovascular] events [in Vioxx users] beginning after 18 months of continuous therapy." Compl. ¶ 321. The falsity of Petitioners' statements regarding their own opinions, however, was not fully revealed until November 1, 2004, when

The Wall Street Journal published excerpts from internal Merck emails demonstrating that Merck had internally concluded years earlier that Vioxx caused adverse cardiovascular events. *See* Pet. App. 19a.

2. The District Court's ruling.

The District Court dismissed on a Rule 12(b)(6) motion all of Respondents' federal securities fraud claims as time-barred based on its characterization of the Complaint, holding that Respondents were on inquiry notice of Petitioners' fraud more than two years before filing the Complaint.

In determining when the statute of limitations began to run on Respondents' claims, the District Court conducted the two-step analysis used by all Courts of Appeals. The first step of that analysis asks whether there were "storm warnings" of the fraud sufficient to cause a reasonable investor to investigate the matter further. If such storm warnings exist, the inquiry proceeds to whether the plaintiff "exercised reasonable due diligence and yet w[as] unable to discover [its] injuries." *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 400 (3d Cir. 2006) (internal quotation marks omitted). In the Third Circuit, a plaintiff who fails to conduct an investigation in response to storm warnings is automatically deemed to fail the second prong of the test, regardless of whether further inquiry would have revealed the wrongful conduct. *See id.* at 401.[5]

In performing this analysis, the District Court, prompted by Petitioners, misapprehended the nature

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[5] Although the Third Circuit had no occasion to reach the issue, Respondents reserve the right to argue that, in the event *certiorari* is granted, a more lenient standard should govern when the second prong is triggered.

of Respondents' claims. The District Court did not address when Respondents were on notice that Petitioners did not actually believe in their naproxen hypothesis. Rather, the District Court considered the different question of when Respondents were on notice that the naproxen hypothesis was unproven or that Vioxx *might* increase the risk of heart attacks. Pet. App. 85a. In other words, the District Court characterized Respondents as alleging that Petitioners failed to disclose that the naproxen hypothesis was a theory rather than a proven fact, when Respondents had made no such argument and Respondents' claims were actually based on Petitioners' lack of good-faith belief in their stated "opinion" that the higher incidence of adverse cardiovascular events among Vioxx users in VIGOR was likely due to a cardio-protective effect of naproxen rather than a harmful effect of Vioxx. Because of this fundamental mischaracterization, the District Court concluded that Respondents were on inquiry notice of their claims no later than October 9, 2001, when a *New York Times* ("*NYT*") article reported both (a) that Merck continued to believe that the naproxen hypothesis was the most likely explanation for the VIGOR results, and (b) that – as had been previously reported since March 2000 – the naproxen hypothesis was unproven and Vioxx might cause heart attacks. *Id.* The District Court also relied on an earlier September 2001 warning letter from the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC"), admonishing Merck for failing to better inform physicians that the naproxen hypothesis was only a theory. *Id.* at 85a-86a. The District Court did not address if or when there were storm warnings that Petitioners misrepresented their own opinion about the naproxen hypothesis.

Because Respondents did not allege that they conducted their own investigation into Petitioners' conduct following the October 9, 2001 *NYT* article, the District Court held that the statute of limitations began to run from that date. *Id.* at 94a, 98a.

3. The Third Circuit's decision.

The Third Circuit reversed the District Court, finding that it had improperly characterized Respondents' claims and that, for the fraud actually alleged, there were no storm warnings before November 6, 2001 – and that Respondents accordingly were not on inquiry notice before that date.

The Third Circuit did not construe the Complaint as alleging that Petitioners misrepresented the fact that the VIGOR trial could support two possible explanations – something that had been clear since March 2000 when Merck first announced the VIGOR results. Instead, the court understood the Complaint to assert that Petitioners' statements of their belief in the naproxen hypothesis were not made in good faith – *i.e.*, that Petitioners "did not hold the belief or opinions expressed." *Virginia Bankshares*, 501 U.S. at 1090-96. The Third Circuit found that, as of November 6, 2001, a reasonable investor would have had no reason to suspect that Petitioners' stated opinions about the validity of the "naproxen hypothesis" were false. *See* Pet. App. 46a ("As of that date, market analysts, scientists, the press, and even the FDA agreed that the naproxen hypothesis was plausible, at the very least. None suggested that Merck believed otherwise.").

Under the Third Circuit's characterization of Respondents' Complaint, the public documents that the District Court believed had provided inquiry

notice were inapposite. As the Third Circuit explained, "Merck had long acknowledged and ... the market had incorporated" the fact that the naproxen hypothesis was an unproven explanation of the VIGOR results (and that the other explanation was that Vioxx caused heart attacks). *Id.* at 43a. Thus, when the DDMAC directed Merck to communicate better to doctors that the naproxen hypothesis was unproven and that Vioxx might cause serious cardiovascular harm, the DDMAC was simply requiring Merck, in the interests of patient safety, to publicize better those facts that had been disclosed previously, and repeatedly, to investors. *See id.* (noting that, in the context of patient safety, consumers – unlike investors – are not presumed to have knowledge of public information about a drug). Similarly, when the *NYT* article reiterated that the naproxen hypothesis was unproven and reported on the DDMAC letter, investors did not learn any "new" information that they did not have since March 2000, when the VIGOR results were released. Pivotally, the DDMAC letter and the *NYT* article "did not charge that the naproxen hypothesis was wrong or that Merck did not believe in the validity of its hypothesis." *Id.* Indeed, Merck continued to promote the naproxen hypothesis as the most likely explanation for the VIGOR results both in the *NYT* article and long afterwards. *See* Compl. ¶ 258. Thus, the court concluded, these documents were not storm warnings to a reasonable investor that Petitioners' statements of opinion were not made in good faith. Pet. App. 43a.

The Third Circuit also held that a handful of pre-November 2001 consumer lawsuits by Vioxx users did not constitute storm warnings. *Id.* at 45a. These

suits "alleged that Merck failed to provide publicly available information to Vioxx consumers." *Id.* Thus, the court determined that those lawsuits were irrelevant to the Complaint's allegations that Petitioners fraudulently misstated their own opinions regarding the naproxen hypothesis to investors. *Id.* Finally, the Third Circuit noted that Merck's stock price and analysts' ratings and projections did not change at the time of the purported storm warnings. *Id.* at 44a-45a. The Third Circuit found that the lack of such changes, though not dispositive, indicated that financial markets did not view the DDMAC letter or the October 2001 *NYT* article as providing new, adverse information about Vioxx. *Id.*

The Third Circuit subsequently denied Petitioners' request for rehearing *en banc*.

4. Respondents' Superseding Amended Complaint.

Following the Third Circuit's reversal, Respondents requested leave to amend their Complaint. Petitioners stipulated to the filing of the new complaint. On March 10, 2009, Respondents filed the new complaint, which reaffirms that the gravamen of Respondents' claims is that Petitioners misled investors by publicly stating that they believed in the naproxen hypothesis when they actually believed that use of Vioxx caused serious cardiovascular harm. *See, e.g.*, Am. Compl. ¶¶ 10-15. Petitioners' motion to dismiss the new, superseding complaint is due on April 17, 2009. The motion will be fully briefed by July 24, 2009.

REASONS FOR DENYING THE PETITION

Petitioners offer no persuasive reason for this Court to grant *certiorari*. There is no division among the circuits on the standard for when a plaintiff has a duty to investigate potential securities fraud or risk running afoul of the statute of limitations. Petitioners take issue with the Third Circuit's application of that standard to Respondents' then-operative Complaint and with the court's interlocutory decision that Respondents did not receive "storm warnings" of the fraudulent scheme that they alleged. But that analysis, conducted on a Rule 12(b)(6) motion to dismiss, is fact-bound, and also of limited relevance given Respondents' filing of a new, superseding complaint after the Third Circuit's decision.

I. THIS CASE DOES NOT IMPLICATE ANY CONFLICT BETWEEN THE CIRCUITS.

As Petitioners concede, there is no circuit split regarding the first prong of the statute of limitations test: when sufficient "storm warnings" exist to trigger a duty to investigate possible fraud. *See* Pet. 3 (noting "general agreement" that no duty to investigate arises until a plaintiff has been "placed on notice of the possibility that it has been defrauded"). The purported division of authority that Petitioners seek to offer deals solely with the second prong of the standard: what actions by the plaintiff, *after* it is under a duty to investigate, affect the running of the limitations period. Because this second prong was not at issue below, the outcome in this case would be identical under any of the supposedly different approaches identified by Petitioners.

A. The Courts of Appeals Apply a Uniform Standard for What Triggers a Plaintiff's Duty To Investigate.

1. The circuits uniformly agree that "storm warnings" are necessary to trigger a duty to investigate.

As every Court of Appeals has recognized, to determine whether a plaintiff is on "inquiry notice" of securities fraud, courts ask whether there were sufficient suspicious facts to "lead a reasonable investor to check carefully into the possibility of fraud." *Young v. Lepone*, 305 F.3d 1, 8 (1st Cir. 2002). That concept – referred to as "storm warnings" – has become the uniform standard among the circuits for triggering inquiry notice. *Id.* (storm warnings analysis "necessarily entails a determination as to whether a harbinger, or series of harbingers, should have alerted a similarly situated investor that fraud was in the wind"); *accord Staehr v. Hartford Fin. Servs. Group, Inc.*, 547 F.3d 406, 411 (2d Cir. 2008); *Merck*, Pet. App. 28a; *Brumbaugh v. Princeton Partners*, 985 F.2d 157, 162 (4th Cir. 1993); *Sudo Props., Inc. v. Terrebonne Parish Consol. Gov't*, 503 F.3d 371, 376 (5th Cir. 2007); *New England Health Care Employees Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003) ("knowledge of suspicious facts – 'storm warnings,' they are frequently called – ... triggers a duty to investigate"); *Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997); *Ritchey v. Horner*, 244 F.3d 635, 640-41 (8th Cir. 2001); *Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 876 (9th Cir. 2008), *petition for cert. pending*, No. 07-1489 (U.S. filed May 27, 2008); *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1203 (10th Cir. 1998); *Tello v. Dean Witter Reynolds, Inc.*, 494 F.3d 956, 968 (11th Cir.

2007) ("Inquiry notice ... occurs when there is factual evidence of the *possibility* of securities fraud that would cause a reasonable person to investigate whether his or her legal rights had been infringed.").

Moreover, the Courts of Appeals have characterized the facts that constitute storm warnings similarly. The circuits agree that a plaintiff "need not ... have fully discovered the nature and extent of the fraud before [he was] on notice that something may have been amiss. Inquiry notice is triggered by evidence of the possibility of fraud, not full exposition of the scam itself." *Kennedy v. Josephthal & Co.*, 814 F.2d 798, 802 (1st Cir. 1987); *see also Staehr*, 547 F.3d at 411; *Brumbaugh*, 985 F.2d at 162 (same); *Fujisawa*, 115 F.3d at 1335 (same); *Tello*, 494 F.3d at 968 (same).[6]

Similarly, "[a]ll ... reported appellate cases are in accord" that, absent storm warnings, plaintiffs have no duty to investigate possible securities fraud claims, and thus cannot be on inquiry notice for pur-

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[6] The Third Circuit noted in *Merck* that it had characterized "storm warnings" in certain prior cases as "evidence alerting an investor to the *probability* of wrongdoing" and in others as "sufficient information of *possible* wrongdoing." Pet. App. 28a. The Third Circuit found these differences to be largely semantic. *Id.* at 29a. It clarified that the underlying inquiry was "whether there was sufficient information of possible wrongdoing ... to excite storm warnings of culpable activity under the security laws" to a reasonable investor. *Id.* at 30a (internal quotation marks omitted). Only the Second Circuit articulates the "storm warnings" standard in terms of "probable," rather than "possible." *See Newman v. Warnaco Group, Inc.*, 335 F.3d 187, 193 (2d Cir. 2003). This phraseology difference appears to involve semantics as well, and even Petitioners do not argue that the Second Circuit's choice of words creates a split that this Court needs to resolve.

poses of the statute of limitations. *LaSalle v. Medco Research, Inc.*, 54 F.3d 443, 444 (7th Cir. 1995). Indeed, Petitioners concede that, under the inquiry notice standard "as typically applied," a plaintiff does not have "a duty to investigate potential claims" until "placed on notice of the possibility that it has been defrauded." Pet. 2-3.

2. The Third Circuit faithfully applied the settled law on "storm warnings."

The Third Circuit applied this settled test for "storm warnings" below. The court held that the duty to investigate potential securities fraud does not begin "until a reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning," and that "storm warnings" exist only if they "put [plaintiffs] on inquiry notice of actionable misrepresentations under the securities laws," rather than some wrongdoing in the abstract. Pet. App. 22a, 35a (internal quotation marks omitted); *see also Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 400 (3d Cir. 2006). The Third Circuit held that "[p]laintiffs need not know all of the details or 'narrow aspects' of the alleged fraud to trigger the limitations period; instead, the period begins to run from the time at which plaintiff should have discovered the general fraudulent scheme." Pet. App. 26a (internal quotation marks omitted; alteration in original).

The Third Circuit reasoned – consistent with every other circuit's approach – that it had to determine whether "storm warnings" of "culpable activity" had arisen in the context of the securities laws violation alleged by Respondents. *See Lampf, Pleva,*

Lipkind, Prupis & Petigrow v. Gilbertson, 501 U.S. 350, 364 (1991) (suit "must be commenced within one year after the discovery of the facts *constituting the violation*") (emphasis added). Here, the gravamen of Respondents' claims is that Petitioners misled investors by stating their belief in the naproxen hypothesis when they did not honestly hold that belief. Thus, the Third Circuit explained that it had to "analyze the existence of storm warnings relative to th[e] allegation" that Merck fraudulently stated its belief in the naproxen hypothesis. Pet. App. 35a. The Court then determined whether, more than two years prior to the filing of Respondents' initial complaint, there were any storm warnings that Merck did not genuinely hold its publicly stated belief in the naproxen hypothesis. The Third Circuit found there were no such storm warnings. *Id.* at 47a. In so finding, the court faithfully applied the uniform law of all circuits.

B. Petitioners Confuse Cases Concerning the Second Prong of the Limitations Test with Cases Implicating the First Prong Issue.

Petitioners assert that the Courts of Appeals use three different "approaches" for determining when the statute of limitations begins to run. Dispositively for this case, however, Petitioners' analysis focuses on an alleged divide in the circuits' application of the *second prong* of the statute of limitations test, which was not the basis for the judgment below.

1. Petitioners' "three approaches" concern only the second prong, not the first.

Petitioners argue that, under what they term the "first approach," the statute of limitations starts immediately after the plaintiff receives storm warnings

(Pet. 20); that under a "second approach" it starts once the plaintiff receives storm warnings and could have detected the fraud by exercising reasonable diligence (Pet. 21); and that the Third Circuit below and the Ninth Circuit in *Betz* follow a "third approach," where the statute of limitations begins to run only after the plaintiff receives storm warnings and subsequently "stumbles upon" direct "evidence of scienter, materiality and loss causation" (Pet. 24).

Even under Petitioners' own characterization of these approaches, none of them differs as to the first step in the analysis: whether sufficient "storm warnings" of the fraud exist in the first place to trigger the second prong requiring a plaintiff to investigate further. Only *after* the plaintiff receives storm warnings – and the first prong of the statute of limitations test is met – do the circuits purportedly employ differing tests to determine when the limitations period is commenced. Because the Third Circuit's decision below rests entirely on applying the first prong of the statute of limitations test, Petitioners' purported circuit conflict is irrelevant to resolving this case.

2. All of the circuits employ the same first prong test for "storm warnings."

A review of the cases that Petitioners cite as evidence of the differing approaches to the *second* prong confirms that there is no circuit split as to the *first* prong. For example, Petitioners argue that the Fourth and Eleventh Circuits follow a "first" approach, while the First, Second, Sixth, Seventh, and Tenth Circuits follow a "second" approach. *See* Pet. 20, 21. But a review of *every* Fourth and Eleventh Circuit opinion cited by Petitioners shows that those cases adopt their inquiry notice standard – including their defini-

tion of "storm warnings" – from First and Seventh Circuit case law.[7] *See, e.g., Theoharous v. Fong*, 256 F.3d 1219, 1228 (11th Cir. 2001) (adopting test in *Kauthar SDN BHD v. Sternberg*, 149 F.3d 659, 670 (7th Cir. 1998)); *Franze v. Equitable Assurance*, 296 F.3d 1250, 1254 (11th Cir. 2002) (citing *Theoharous*); *Brumbaugh*, 985 F.2d at 162 (adopting test in *Kennedy*, 814 F.2d at 802); *GO Computer, Inc. v. Microsoft Corp.*, 508 F.3d 170, 178 (4th Cir. 2007) (citing *Brumbaugh*).

Likewise, Petitioners argue that the Fifth and Eighth Circuits "sometimes" adopt the "first" approach. *See* Pet. 20-21. However, *every* Fifth and Eighth Circuit opinion cited by Petitioners adopts its test for storm warnings from First, Second, and Tenth Circuit case law, which purportedly follow the "second" approach. *See, e.g., Jensen v. Snellings*, 841 F.2d 600, 607 (5th Cir. 1988) (adopting test in *Armstrong v. McAlpin*, 699 F.2d 79, 88 (2d Cir. 1983), and *Cook v. Avien, Inc.*, 573 F.2d 685, 697-98 (1st Cir. 1978)); *Bodenhamer v. Shearson Lehman Hutton, Inc.*, No. 92-2392, 1993 WL 277033, at *2 (5th Cir. July 14, 1993) (judgment noted at 998 F.2d 1013) (citing *Jensen*); *Great Rivers Coop. v. Farmland Indus., Inc.*, 120 F.3d 893, 896 (8th Cir. 1997) (citing *Davidson v. Wilson*, 973 F.2d 1391, 1402 (8th Cir. 1992), which adopted the test in *Anixter v. Home-Stake Production Co.*, 939 F.2d 1420, 1437 (internal quotation marks omitted), *amended on other grounds on denial of*

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[7] At least one First Circuit case cited by Petitioners as falling under their so-called "second" approach explicitly adopts the Third Circuit's statute of limitations test – which Petitioners assert falls under a "third approach." *See Young*, 305 F.3d at 8 (adopting test in *Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239, 251 n.14 (3d Cir. 2001)).

reh'g, 947 F.2d 897 (10th Cir. 1991), *vacated and remanded on other grounds sub nom. Dennler v. Trippet*, 503 U.S. 978 (1992), and *Cook*, 573 F.2d at 696-97).

Similarly, notwithstanding Petitioners' assertion that the Third Circuit in the present case and the Ninth Circuit in *Betz* adopted yet a third "approach," those decisions demonstrate that both courts enunciated and intended to apply the same standard for storm warnings as every other circuit. In *Betz*, the Ninth Circuit expressly adopted the same inquiry notice test that all other circuits apply: "[a] plaintiff is on inquiry notice when there exists sufficient suspicion of fraud to cause a reasonable investor to investigate the matter further." 519 F.3d at 876. Indeed, the Ninth Circuit specifically relied on and adopted the cases that, according to Petitioners, follow a conflicting approach. *Compare id.* at 876-77 (citing with approval *Sterlin*, *Fujisawa*, and *Great Rivers*) *with* Pet. 21-22 (arguing that the test in *Betz* differs from *Sterlin*, *Fujisawa*, and *Great Rivers*).

In the present case, the Third Circuit heavily relied on its prior decisions, *see* Pet. App. 23a-24a, 28a, which made clear that the court viewed "[t]he general articulation of the inquiry notice standard ... [a]s fairly consistent." *Mathews*, 260 F.3d at 251. The Third Circuit endorsed just that "consistent articulation" below by adopting the very cases that Petitioners cite as demonstrating a circuit split. *Compare id.* at 251 n.15 (citing *Great Rivers* as evidence that the Courts of Appeals use the same standard for inquiry notice) *with* Pet. 21 (citing *Great Rivers* as evidence that the Courts of Appeals do not use the same standard for inquiry notice); *compare also* Pet. App. 29a-30a (citing *Fujisawa* as using a

"similar[]" test as the Third Circuit) *with* Pet. 22 (citing *Fujisawa* as using a different test from the Third Circuit).

C. Respondents' Claims Would Be Timely Under Any of the Putatively Different Tests Proffered by Petitioners.

Because all the circuits use the same test to determine whether there are storm warnings of fraud, this case would not have come out differently in any other Court of Appeals.

Petitioners argue that, under the law of any circuit other than the Ninth and Third Circuits, plaintiffs' claims would be untimely. *See* Pet. 25. That is incorrect. The Third Circuit found, as a factual matter, that there was no reason to suspect that Petitioners did not believe in the naproxen hypothesis until at least October 2003, when the results of the Brigham study were published. *See* Pet. App. 18a, 46a-47a. Because "market analysts, scientists, the press and even the FDA agreed that the naproxen hypothesis was plausible, at the very least," *id.* at 46a, plaintiffs had no hint that Petitioners did not actually believe in their naproxen hypothesis.[8] Without such storm

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[8] Petitioners complain that the Third Circuit adopted a new test for storm warnings in considering how Merck's stock price was affected by various disclosures. *See* Pet. 24 n.9. However, the Third Circuit expressly stated the opposite, noting that it was not establishing a per se rule that storm warnings do not exist in the absence of declines in the stock price or analyst's ratings. *See* Pet. App. 47a n.16. In an open market securities action, it is logical that the reaction of a company's stock to news is a factual indicator of whether the information is new, material, or suspicious, and, thus, is relevant to whether information constitutes storm warnings. If the market or analysts do not react to information with suspicion, it follows that a reasonable investor generally would not either.

warnings, Respondents had no duty to investigate under any of the circuits' tests, and the statute of limitations was not triggered. *See LaSalle*, 54 F.3d at 444.

The Third Circuit below faced a question of first impression in applying the uniform inquiry notice standard to a claim that defendants had misrepresented their own opinion on a scientific issue. Applying the first prong of the statute of limitations test adopted by every circuit, the Third Circuit found that that prong could not be met until Respondents had some reason to believe Petitioners did not or could not believe that opinion when they offered it.

Petitioners argue that the Second Circuit would have decided this case differently, pointing to a district court decision in *In re Zyprexa Products Liability Litigation*, 549 F. Supp. 2d 496, 535-36 (E.D.N.Y. 2008), and the non-precedential decision in *Masters v. GlaxoSmithKline*, 271 F. App'x 46, 49 (2d Cir. 2008). *See* Pet. 26. However, the complaints in those cases dealt with misstatements of material fact, not with misstatements of opinion. Petitioners' argument rests on (a) repeating the District Court's mischaracterization of Respondents' claims and (b) assuming, counterfactually, that storm warnings existed. By publicly disclosing the results of the VIGOR trial, while simultaneously attributing those results to a hypothesis that even the FDA noted was a possible explanation of the VIGOR results – *but that Petitioners themselves believed to be false* – Petitioners avoided creating storm warnings of their misconduct. Because there were no storm warnings that Petitioners did not believe the naproxen hypothesis was true, under either Third or Second Circuit case law the statute of limitations was not triggered.

Petitioners also contend that this case would have come out differently in the First, Fifth, Sixth, Seventh, and Eighth Circuits because "[i]n these circuits ... the timeliness of respondents' claims would depend upon the results of a reasonable diligent investigation." Pet. 27. However, none of these circuits would have considered the "results of a reasonable diligent investigation" because none would have required a reasonable investor to conduct such an investigation in the absence of storm warnings. [9]

II. THE THIRD CIRCUIT'S INTERLOCUTORY ORDER IS CONSISTENT WITH THIS COURT'S DECISION IN *LAMPF*.

The Third Circuit's decision comports with this Court's opinion in *Lampf*, with the statute, and with the goals of inquiry notice. In *Lampf*, this Court held that "[l]itigation instituted pursuant to § 10(b) ... must be commenced within one year after the discovery of *the facts constituting the violation*." 501 U.S. at 364 (emphasis added). The codification of the statute of limitations in § 1658(b) similarly states that an action may not be brought later than "2 years after the discovery of the *facts constituting the violation*." 28 U.S.C. § 1658(b) (emphasis added). Thus, a proper analysis of the statute of limitations must take account of what "violation" is alleged.

Petitioners, like the District Court below, misapprehend the "violation" of the securities laws that Respondents allege, and thus confuse the issue of

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[9] Petitioners also assert that Respondents' claims would have been time-barred in the Eleventh or Fourth Circuit. *See* Pet. 25. However, Petitioners do not explain why that is so and merely quote the inquiry notice test in those circuits – which use the same language as the Third Circuit below.

when a duty to investigate that potential violation arose. Petitioners assert that there were storm warnings that "petitioners made knowing misrepresentations regarding the safety of [Vioxx]." Pet. 4. However, as the Third Circuit recognized, Respondents' "theory in the complaint is that Merck's statements about the validity of the naproxen hypothesis were falsely-held statements of opinion or belief." Pet. App. 33a-34a. *Lampf* and § 1658(b) require that any statute of limitations analysis take a proper understanding of the alleged fraud as its starting point. Petitioners' attack on the Third Circuit's opinion is off point because they address the wrong "violation."

Given a proper understanding of Respondents' claims, the Third Circuit's decision clearly comports with the goals of inquiry notice. Inquiry notice exists to prevent an investor who suspects securities fraud from "sit[ting] back ... so that he could see how the price of his stock behaved in the interim." *Fujisawa*, 115 F.3d at 1337; *accord Mathews*, 260 F.3d at 254. However, "[i]nquiry notice ... must not be construed so broadly that the statute of limitations starts running too soon for the victim of the fraud to be able to bring suit ... . The facts constituting such notice must be sufficiently probative of fraud – sufficiently advanced beyond the stage of a mere suspicion." *Fujisawa*, 115 F.3d at 1335; *see also Law v. Medco Research, Inc.*, 113 F.3d 781, 786 (7th Cir. 1996) (same). That concern is particularly important with respect to the statute of limitations for securities fraud claims, which must meet the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA"), 15 U.S.C. § 78u-4(b). *See* Pet. App. 30a.

Petitioners broadly suggest that hints of *any* misdeeds by a defendant – such as Merck's inadequately balanced sales presentations at issue in the consumer lawsuits and the DDMAC's warning letter – should trigger the statute of limitations for a securities fraud claim. *See* Pet. 30-31. However, there is no rule "that notice of one wrong by a defendant triggers a duty for potential plaintiffs to investigate all other potential wrongs the defendant might be committing." *Morton's Market, Inc. v. Gustafson's Dairy, Inc.*, 198 F.3d 823, 834 (1999), *amended in part on other grounds*, 211 F.3d 1224 (11th Cir. 2000); *see also La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 848 (11th Cir. 2004) (same); *cf. Marine Bank v. Weaver*, 455 U.S. 551, 556 (1982) ("Congress, in enacting the securities laws, did not intend to provide a broad federal remedy for all fraud."). The inquiry notice standard does not require investors to launch a wild-goose chase for evidence of securities fraud simply because they receive hints that a defendant has committed a different type of wrongdoing (*e.g.*, has run afoul of laws regulating the safety of products or has provided inadequate warnings to consumers of a drug).

Petitioners' other arguments that the Third Circuit's decision frustrates the policy behind the statute of limitations likewise fail.

First, Petitioners contend that the Third Circuit's decision removes the "investigation" step from the statute of limitations test. *See* Pet. 28. That is incorrect. The Third Circuit never reached the investigative step under the facts of this case because there were no storm warnings to prompt an inquiry or investigation in the first place. The two-pronged statute of limitations test only requires the investor

to investigate if there is adequate reason – namely, storm warnings – to do so.

Second, Petitioners claim that the Third Circuit's decision encourages plaintiffs to disregard storm warnings. *See* Pet. 29. Again, that is incorrect: the Third Circuit found that there were no storm warnings, and its decision has no bearing on what an investor should have done had there been such warnings.

Third, Petitioners complain that the Third Circuit's decision forces defendants to choose between arguing that the plaintiff had sufficient evidence of fraud to trigger the duty to investigate and arguing that the plaintiff has insufficient evidence to bring a claim under Rule 12(b)(6). *See* Pet. 29-30. Of course, defendants can and regularly do make both arguments in the alternative. In any event, that tension is inherent between *any* inquiry notice standard and Rule 12(b)(6).

III. THIS CASE IS FACT-BOUND AND, IN ANY EVENT, THE DISTRICT COURT SHOULD BE PERMITTED IN THE FIRST INSTANCE TO EVALUATE STATUTE OF LIMITATIONS ARGUMENTS UNDER THE NEW COMPLAINT.

The decision below did not turn on the appropriate legal standard for inquiry notice. Rather, it was based on a detailed factual analysis of the information available to Respondents and of Respondents' Complaint. Indeed, the latter analysis may be moot because Respondents have since filed a new complaint.

A. The Third Circuit's Decision To Reverse the District Court Turned on the Specific Facts Surrounding Respondents' Claims, Not on the Inquiry Notice Standard.

Importantly, in reaching contrary conclusions, the Third Circuit and the District Court did *not* disagree on the legal standard for inquiry notice. *Compare* Pet. App. 83a-84a *with id.* at 23a-24a. The District Court came to an incorrect result because it misapprehended the nature of Respondents' claims and, therefore, misunderstood the import of information surrounding the VIGOR trial. The two courts disagreed in their fact-bound interpretations of Respondents' Complaint and in their assessment of the very different claims that they perceived Respondents to have made against the publicly available information. *See id.* at 31a-47a (applying the inquiry notice standard to the publicly available information).

The Courts of Appeals agree that "[t]he determination of *when* inquiry notice occurred ... [is] necessarily fact-specific to each case." *Tello v. Dean Witter Reynolds, Inc.*, 410 F.3d 1275, 1284 (11th Cir. 2005); *see also Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 169 (2d Cir. 2005) ("Our recent decisions reinforce the fact-specific nature of the limitations defense, particularly where the claim is foreclosed by inquiry notice."); *Young*, 305 F.3d at 9 ("The multifaceted question of whether storm warnings were apparent involves issues of fact. In the archetypical case, therefore, it is for the factfinder to determine whether a particular collection of data was sufficiently aposematic to place an investor on inquiry notice.") (citation omitted). This case, in particular, hinges not on any question relating to the legal standard for inquiry notice, but instead on the proper characterization of Respondents' factual allegations.

B. Petitioners Have Consented to the Filing of Respondents' Amended Complaint, So the District Court Should Analyze Any Remaining Statute of Limitations Arguments in the First Instance.

The District Court initially erred in finding storm warnings of securities fraud because it misinterpreted Respondents' Complaint. While the Third Circuit correctly held that Respondents alleged fraudulent statements of opinion, Respondents filed a new Complaint on March 10, 2009, that clearly alleges that Petitioners made false statements of opinion when they expressed their belief in the naproxen hypothesis. *See* Am. Compl. ¶ 145. Petitioners consented to the filing of the Amended Complaint. The lower court decisions were predicated on Respondents' prior Complaint dated June 14, 2005. The operative complaint in the case has subsequently changed – without Petitioners' opposition. Therefore, it should be the District Court in the first instance that rules on whether Respondents' operative complaint is barred by the statute of limitations. *See, e.g., Vega-Encarnación v. Babilonia*, 344 F.3d 37, 42 (1st Cir. 2003) ("The limitations defense ... should be addressed in the first instance in the district court.").[10]

IV. THE SPECIFIC STATUTE OF LIMITATIONS QUESTION PRESENTED BELOW WILL RARELY RECUR.

Any decision by this Court to address the standards for inquiry notice ought to involve a recurring fact pattern. The decision below arose in the unusual

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[10] The briefing schedule for Petitioners' motion to dismiss the superseding Amended Complaint is noted at page 13 above.

context of a securities fraud claim based on a misrepresentation of an *opinion*. In this case (1) Petitioners disclosed the results of the VIGOR trial even though one interpretation of the study called into question Vioxx's safety; (2) there was a scientific debate among third parties – including doctors and the FDA – over whether the results of the VIGOR trial were attributable to the cardio-protective effects of naproxen or the adverse effects of Vioxx; and (3) Petitioners publicly stated their belief that the naproxen hypothesis was correct, even though they had reached a contrary conclusion internally and did not genuinely hold that belief.

In sum, Respondents alleged that Petitioners made false statements of opinion concerning a hypothesis that they did not believe was true, in circumstances where third parties (doubtless influenced by Merck) subsequently embraced that hypothesis. This unusual constellation of circumstances arose in part because of the complexity of the underlying scientific question on which Petitioners stated their opinion, as well as the lack of definitive public studies of Vioxx and naproxen's effects on cardiovascular events. Respondents are aware of no securities fraud case outside the Third Circuit analyzing storm warnings in an analogous context.[11] Thus, there is no division

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[11] A recent Third Circuit case, *Alaska Electrical Pension Fund v. Pharmacia Corp.*, 554 F.3d 342, 347 (3d Cir. 2009), also involves "interpretation" of clinical trial results and a claim that the defendant fraudulently misstated its own opinion. There, the court considered whether plaintiffs were put on inquiry notice that drugmaker Pharmacia had engaged in culpable activity where information provided at a public FDA meeting confirmed that Pharmacia had not disclosed certain clinical study data, but where there was no suggestion that Pharmacia did not believe its publicly stated opinion that it had properly

of authority in the circuits on how the inquiry notice standard applies to misstatements of opinion. Moreover, the lack of a developed jurisprudence in this context suggests that this case involves an unusual fact pattern and that the petition raises questions of narrow applicability.

In any event, Petitioners wrongly assert that this case underscores the lack of uniformity among the

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excluded those data for valid scientific reasons. *Id.* at 349. In that factual context, the Third Circuit held that "[t]he mere fact ... that there was a technical dispute between scientists about whether to use the full data or only a portion of the data, would not have provided storm warnings of fraud to the reasonable investor," *id.* at 350, and that, for storm warnings, "there must be *some indication* that defendants did not, in fact, hold the views expressed," *id.* at 348 (emphasis added). The court did not find the requisite "some indication" until a later *Washington Post* article suggested that Pharmacia had "massaged" certain trial data and also withheld information from the medical journal that published an article on the trial's findings. Although the *Pharmacia* opinion states that "*Merck* found that inquiry notice ... requires storm warnings indicating that defendants acted with scienter," *id.*, the *Merck* decision never used that language. Read in context, *Pharmacia*'s use of the term "scienter" was shorthand for its application of the false opinion/inquiry notice test actually employed in *Merck*, which *Pharmacia* then accurately quotes: "'[T]o trigger storm warnings of culpable activity, in the context of a claim alleging falsely-held opinions or beliefs, investors must have sufficient information to suspect that the defendants engaged in culpable activity, i.e., *that they did not hold those opinions or beliefs in earnest.*'" *Id.* (quoting Pet. App. 33a). Thus, to find "storm warnings," *Pharmacia* ultimately required only "some indication" of a "possibility of fraud," *id.* at 350, and certainly not the quantum of evidence that would enable a plaintiff to plead scienter under the PSLRA. *See, e.g., id.* at 351 n.10 ("We note that inquiry notice ... is alive and well in this Court. ... Here, we merely conclude that, in the absence of *any indication* that defendants did not believe the truth of their own statements, investors were not on inquiry notice of § 10(b) claims.") (emphasis added).

circuits on the standard for inquiry notice. *See* Pet. 32. Each Court of Appeals employs the same test to determine if storm warnings are present and the duty to investigate is triggered. *See* pp. 15-16, *supra*. Petitioners essentially assert that, on the very same facts, the case would have come out differently in some other court. But there is no basis for thinking that the Courts of Appeals do not apply the same legal standard in the same way. *See Tello*, 410 F.3d at 1284.

V. THIS CASE NEED NOT BE HELD FOR *BETZ*.

This Court has invited the Solicitor General to file a brief expressing the views of the United States on the pending petition for *certiorari* in *Betz*. *See Trainer Wortham & Co. v. Betz*, No. 07-1489 (U.S. filed May 27, 2008). There is no need to hold this case pending any decision by the Court in *Betz*.

Betz articulated the first prong of the statute of limitations test in the same manner as every other circuit. *See* p. 15, *supra*. Even Judge Kozinski, in dissenting from the denial of rehearing *en banc* in *Betz*, agreed that the Courts of Appeals have adopted a uniform standard with respect to the type of information that puts a plaintiff on notice: "[a]ccording to the same ten circuits, the statute of limitations starts to run ... when a reasonable investor in plaintiff's position would suspect he had been defrauded." 519 F.3d at 866. Judge Kozinski took issue not with that standard – which *Betz* explicitly adopted – but rather with the application of that standard to the facts in *Betz*. *See id.* ("The panel pretends to adopt this standard, but rejects it in fact."). Because the particular manner in which the *Betz* panel applied that univer-

sal standard to the facts before it has no bearing on the Third Circuit's application of the standard to the different – and unusual – facts of this case, there is no reason to hold this case for *Betz*.

CONCLUSION

The petition for a writ of *certiorari* should be denied.

Respectfully submitted.

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REPLY BRIEF

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IN THE

Supreme Court of the United States

MERCK & CO., INC., *ET AL.*,

Petitioners,

v.

RICHARD REYNOLDS, STEVEN LEVAN, JEROME HABER, *ET AL.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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It cannot seriously be disputed that the Courts of Appeals are sharply divided on the proper interpretation of the "inquiry notice" standard for the accrual of securities fraud claims. Indeed, since this petition was filed, the Third Circuit has issued an opinion in another case that reaffirms the split and solidifies the Third Circuit's position on the outskirts of inquiry notice jurisprudence. *See Alaska Elec. Pension Fund v. Pharmacia Corp.*, 554 F.3d 342 (3d Cir. 2009). As the petition explained at length, the conflict among the Courts of Appeals will frequently prove to be outcome-determinative, leading to irreconcilable results that underscore the need for a uniform, nationwide standard – a need that this Court expressly recognized in *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991).

Faced with an undeniable circuit split, Respondents are left to argue that this case constitutes an inappropriate vehicle for addressing any division among the Courts of Appeals. In fact, this case is an ideal vehicle for resolving the conflict, and the Court may have a dwindling number of opportunities to resolve it in the future. The petition should therefore be granted.

I. The Decision Below Directly Implicates a Case-Dispositive Circuit Conflict.

Respondents make the remarkable assertion that "there is no division among the circuits" on the inquiry notice standard because every Court of Appeals, including the Third Circuit, uses the phrase "storm warnings" in its articulation of the standard. (Opp. at 14-17.) Respondents entirely ignore the fundamental differences among the circuits in their

applications of the standard. As the petition sets forth in detail (Pet. at 18-27), the Courts of Appeals are split in at least two critical (and independently outcome-dispositive) respects.[1]

The first split among the Courts of Appeals concerns the type of information sufficient to trigger an investor's duty to investigate potential fraud. Whereas most Courts of Appeals hold that suspicious circumstances or facts tending to suggest a misrepresentation constitute "storm warnings," the Third and Ninth Circuits hold that "storm warnings" exist only when there is evidence of *all* of the specific elements of an investor's claim, including scienter. (*See* Pet. at 4-5, 23-25.) Respondents' only answer – that no division exists because the Courts of Appeals consistently use the phrase "storm warnings" (Opp. at 14-17) – is no response at all. It simply ignores the fact that the Third and Ninth Circuits *define* "storm warnings" in a manner different from, and flatly inconsistent with, the other Courts of Appeals. *See Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 867-69 (9th Cir. 2008) (Kozinski, J., dissenting from denial of rehearing *en banc*) (noting that "ten circuits disagree" with the "curious notion" that "an investor isn't on inquiry notice until he has concrete proof of every element of his claim, including scienter").

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[1] These divisions are also detailed in the petition for *certiorari* filed in *Trainer Wortham & Co. v. Betz*, No. 07-1489 (filed May 27, 2008), and the amicus brief submitted in support of that petition by the Organization for International Investment and the United States Chamber of Commerce (filed June 30, 2008).

The second split concerns the start date of the limitations period, with some Courts of Appeals starting the limitations clock on the date that "storm warnings" arose and others doing so on the date that an investor, exercising reasonable diligence, could have uncovered the alleged fraud. (*See* Pet. at 3, 20-22.) Respondents do not even attempt to address this split, which has been explicitly recognized by several Courts of Appeals. *See New Eng. Health Care Employees Pension Fund v. Ernst & Young LLP*, 336 F.3d 495, 501 (6th Cir. 2003); *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1200 (10th Cir. 1998).

Since the petition in this case was filed, the Third Circuit has issued yet another opinion that reaffirms its approach and highlights the division among the Courts of Appeals. *See Pharmacia*, 554 F.3d 342. In that case, the plaintiffs alleged that the defendants, two pharmaceutical companies and several of their employees, violated section 10(b) and Rule 10b-5 by distorting study results to show that a particular drug had a more favorable safety profile than its competitors. In overturning the dismissal of the complaint on limitations grounds, the Third Circuit reiterated its holding in this case that "storm warnings" do not arise until a plaintiff has evidence of the specific elements of its claim. The court specifically recognized that "*Merck* found that inquiry notice, in securities fraud suits, requires storm warnings indicating that defendants acted with scienter." *Id.* at 348. Critically for present purposes, the court emphasized that evidence of scienter is required because scienter is "elemental" to a federal securities fraud claim. *Id.* Because there was no such evidence of scienter, the court held that no "storm warnings"

existed. *Id.* at 351 & n.10. Moreover, as it did in this case, the court based its conclusion in part on the fact that securities analysts had not altered their ratings of the corporation and the fact that there was insufficient evidence linking the decline in the price of the corporation's stock to the alleged fraud. *Id.* at 349, 350 n.9.[2]

Apart from the Ninth Circuit in *Betz*, no other Court of Appeals has ever endorsed this standard, and many have rejected it. *See, e.g., Theoharous v. Fong*, 256 F.3d 1219, 1228 (11th Cir. 2001) (holding that "storm warnings" do not require evidence of scienter); *Sterlin*, 154 F.3d at 1203 (holding that a single article created "storm warnings" despite the fact that "nothing in the article even 'raise[d] the possibility' that [d]efendants made knowing misrepresentations"). In those circuits, evidence of a misrepresentation creates "storm warnings" of possible fraud, without regard to whether there was evidence that the misrepresentation was made knowingly or recklessly – that is, with scienter. *See, e.g., Masters v. GlaxoSmithKline*, 271 Fed. Appx. 46, 49 (2d Cir. 2008); *Great Rivers Coop. v. Farmland Indus., Inc.*, 120 F.3d 893, 897 (8th Cir. 1997); *LaSalle v. Medco Research, Inc.*, 54 F.3d 443, 446-47 (7th Cir. 1995);

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[2] *Pharmacia* illustrates the way in which the Third Circuit test makes it virtually impossible for a defendant to argue for dismissal both on statute of limitations and insufficiency of the pleadings grounds. (*See* Pet. at 29-30.) In *Pharmacia*, the Third Circuit interpreted the defendants' argument that the plaintiffs had failed to plead a material misrepresentation as a concession that "storm warnings" did not exist. *See* 554 F.3d at 350 n.7.

see also Betz Pet. at 16-19 (citing other cases). Those circuits hold that scienter is relevant to the statute of limitations analysis, if at all, only at the second step: that is, for purposes of determining whether a reasonably diligent investigation could have uncovered the facts on which a plaintiff's claims are based.[3]

Contrary to Respondents' assertion, therefore, this case would have come out differently if it had been filed in another circuit.[4] Under either the first or second approaches discussed in the petition (*see* Pet. at 20-23), a court would necessarily find that the FDA warning letter, the consumer fraud lawsuit, the

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[3] *See, e.g., Levitt v. Bear Stearns & Co.*, 340 F.3d 94, 103 (2d Cir. 2003) (considering scienter at "reasonable investigation" step); *Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997) (connecting pleading standards under Rule 9(b) with the ease of obtaining details of the alleged fraud through diligent investigation); *see also Wyser-Pratte Mgmt. Co. v. Telxon Corp.*, 413 F.3d 553, 564-67 (6th Cir. 2005) (in applying federal inquiry notice standard to state law fraud claims, stating that the ability to discover evidence of scienter was relevant to whether the plaintiff could have discovered the fraud through investigation).

[4] Respondents' argument to the contrary is based on the erroneous premise that "[t]he decision below did not turn on the appropriate legal standard for inquiry notice" but rather "on a detailed factual analysis." (Opp. at 27-28.) The clear language in the opinion below and in *Pharmacia* squarely contradicts this argument. (*See supra* p. 3; *infra* p. 6-7.) It is particularly disingenuous for Respondents to assert otherwise given that they argued for reversal on the ground that the District Court applied the incorrect legal standard. (*See* Resp. C.A. Br. at 31 ("[I]n order for storm warnings of a securities fraud claim to exist, plaintiffs must be on notice that the alleged false statements and omissions were made *with scienter*." (emphasis in original)).)

three product liability lawsuits, and the flood of analyst reports and news articles, including the October 9, 2001 *New York Times* article, created "storm warnings" of fraud because they provided sufficient reason to doubt whether Merck's statements concerning the cardiovascular safety of Vioxx were in fact true. (*See* Pet. at 25-27.)

II. This Case is an Optimal Vehicle for Resolving the Circuit Conflict.

As set forth in the petition, this case is an archetypical securities fraud class action that was decided on a pure issue of law and with undisputed facts. (*See* Pet. at 33-35.) Respondents make two arguments for why this case is nevertheless an inappropriate vehicle for reviewing the proper interpretation of the inquiry notice standard. They are wrong on both counts.

First, Respondents argue that this case presents an issue of "narrow applicability" that will "rarely recur" because it involves the proper inquiry notice standard only for alleged "misstatements of opinion," and not "misstatements of material fact." (Opp. at 23, 29-31.) This distinction is one without a difference. Regardless of the nature of the alleged misrepresentation, a plaintiff in a securities fraud action under section 10(b) must come forward with evidence of scienter. To be sure, a claim of a misrepresentation of fact requires a showing that the defendant knew that his statement was false, whereas a claim of misrepresentation of opinion requires a showing that the defendant knew that its asserted opinion did not have a basis in fact. *See Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1095-96 (1991).

That subtle distinction, however, has no relevance to the resolution of the question presented, which concerns the proper interpretation of the inquiry notice standard applicable to *all* securities fraud claims under section 10(b).[5] As the Third Circuit's subsequent decision in *Pharmacia* confirms, the opinion below adopts a general rule, applicable to all section 10(b) claims, that "storm warnings" do not arise unless evidence of all of the elements of a claim, including scienter, are present. *See, e.g.*, *Pharmacia*, 554 F.3d at 348 (holding that "storm warnings" of a section 10(b) claim require evidence of scienter because scienter is "elemental" to all such claims).[6]

Second, Respondents argue that the filing of their amended complaint in the District Court makes this case ill suited for this Court's review. (Opp. at 29.) The amended complaint, however, has no effect on this petition and thus does not deprive Petitioners

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[5] In light of the nearly identical question presented by the petition here and the petition filed in *Betz* (*compare* Pet. at i *with Betz* Pet. at i), Respondents' assertion that this Court need not hold the petition if it were to grant review in *Betz* (Opp. at 32-33) cannot be taken seriously.

[6] Respondents attempt to distinguish *Masters v. GlaxoSmithKline*, 271 Fed. Appx. 46 (2d Cir. 2008), which upheld dismissal of a nearly identical suit on statute of limitations grounds, on the basis that *Masters* involved "misstatements of material fact." (Opp. at 23.) That effort is unavailing. Like this case, *Masters* involved alleged misrepresentations about a drug's safety and the purported failure to disclose an allegedly known link to adverse effects. *See Masters*, 271 Fed. Appx. at 48. There is simply no support for Respondents' assertion that the Second Circuit would apply a different statute of limitations test in a self-styled "misstatement[] of opinion" case. (Opp. at 23.)

of their ability to seek review of the opinion below. As Respondents concede, the amended complaint alleges the same fraud asserted in the prior complaint (*see* Opp. at 13). Accordingly, it would be futile for Petitioners to challenge the timeliness of Respondents' section 10(b) claim in response to the amended complaint; the Court of Appeals has already ruled on that issue and there is no basis for the District Court to revisit that ruling. Unsurprisingly, Respondents make no effort to argue that the amended complaint differs from the prior complaint in any way relevant to the Third Circuit's analysis.

There is similarly no merit in Respondents' suggestion that the Third Circuit's decision is unreviewable simply because it is interlocutory. (*See* Opp. at 14, 24.) That suggestion ignores the critical importance of the pleading stage in a securities fraud class action. (*See* Pet. at 34.) As this Court has explained, given the enormous pressure on defendants to settle before trial, there is often no opportunity after the pleading stage to review lower court decisions. *See Merrill Lynch, Pierce, Fenner & Smith v. Dabit*, 547 U.S. 71, 80-81 (2006). Perhaps for that reason, virtually all of this Court's recent decisions involving private securities fraud actions have been in a similarly interlocutory posture. *See, e.g., Lampf*, 501 U.S. at 353-54; *see also Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 128 S. Ct. 761 (2008); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007); *Dabit*, 547 U.S. at 71; *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336 (2005).

Given the recurring and important nature of the issue presented by the petition, this Court should intervene now. In the nearly twenty years that have

passed since this Court's decision in *Lampf*, every circuit that has addressed the issue has formed a well-developed body of inquiry notice jurisprudence. The conflict presented by the petition is thus fully mature, and further percolation would serve no purpose.

Indeed, if the plaintiff-friendly inquiry notice standard adopted by the Third and Ninth Circuits is not reviewed now, it may be difficult to resolve the resulting circuit conflict in the future. Under the standard applied by the Third and Ninth Circuits, it is extremely unlikely that securities fraud actions filed within those circuits will be dismissed on inquiry notice grounds. (*See* Pet. at 30-31 ("[T]he only claim that will be time-barred is one where all potential plaintiffs somehow neglect to bring suit after having specific evidence of the elements of their claims for more than two years.").) Because securities fraud cases are rarely litigated to a final judgment, the application of that standard in subsequent cases will likely evade meaningful appellate review. And although, theoretically, the Court could review the question presented by the petition in a case arising from another circuit, the pool of available cases is likely to dwindle as plaintiffs elect to file securities fraud actions in the Third and Ninth Circuits. This type of forum shopping directly contravenes the spirit of this Court's decision in *Lampf* and underscores the need for review now.

Nothing will be gained by waiting for another case to present similar issues. The question presented in this case is of national importance, and this case constitutes an optimal vehicle for the resolution of that question.

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For the foregoing reasons and those stated in the petition, the petition for a writ of *certiorari* should be granted.

April 7, 2009

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JOINT APPENDIX

Supreme Court, U.S.
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No. 08-905

In the Supreme Court of the United States

MERCK & CO., INC., ET AL., PETITIONERS

v.

RICHARD REYNOLDS, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

JOINT APPENDIX
(VOLUME 1; PAGES 1-507)

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PETITION FOR A WRIT OF CERTIORARI FILED: JANUARY 15, 2009
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UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

Case Nos. 07-2431 & 07-2432

IN RE: MERCK & CO., INC. SECURITIES, DERIVATIVE & "ERISA" LITIGATION

DOCKET ENTRIES

DATE	PROCEEDINGS
	* * * * *
08/03/2007	ELECTRONIC BRIEF on behalf of Appellants in 07-2431 and 07-2432, Copies: 1, Pages: 58, Word Count: 13,713, delivered by mail, filed. Certificate of service date 8/3/07.
08/06/2007	HARD COPY RECEIVED of Brief from Appellants in 07-2431 and 07-2432, Copies: 10.
	* * * * *
10/02/2007	ELECTRONIC BRIEF on behalf of Appellees in 07-2431 and 07-2432, Copies: 1, Pages: 54, Word Count: 13,964, delivered by mail, filed. Certificate of service date 10/2/07.
	* * * * *

DATE	PROCEEDINGS
10/03/2007	HARD COPY RECEIVED from Appellees in 07-2431 and 07-2432 submitting 10ccs of brief.
	* * * * *
10/26/2007	ELECTRONIC REPLY BRIEF on behalf of Appellants in 07-2431 and 07-2432, Copies: 1, Word Count: 6,987, Delivered by mail, filed. Certificate of service date 10/26/07.
10/29/2007	HARD COPY RECEIVED of Reply Brief on behalf of Appellants in 07-2431 and 07-2432, Copies: 10.
	* * * * *
06/24/2008	ARGUED on Tuesday, June 24, 2008 in Newak, NJ before SLOVITER, BARRY and ROTH, Circuit Judges. Evan R. Chesler arguing for Appellees Merck & Co Inc, Raymond V. Gilmartin, Kenneth C. Frazier, Richard C. Henriques, Jr., Peter S. Kim, Judy C. Lewent, Alise S. Reicin, Lawrence A. Bossidy, William G. Bowen, Jeanetta B. Cole, William B. Harrison, Jr., William N. Kelley, Heidi G. Miller, Thomas E. Shenk, Anne M. Tatlock, Samuel O. Thier, David Anstice, Richard T. Clark, Celia Colbert, Linda M. Distlerath, Caroline Dorsa, Bernard J. Kelley, Per GH Lofberg, Per Wold Olsen, Lloyd C. Elam, and Edward M. Scolnick; John P.

DATE	PROCEEDINGS
	Coffey arguing for Appellants Pub Empl Ret Sys MS. [07-2431, 07-2432]
	* * * * *
09/09/2008	PRECEDENTIAL OPINION Coram: SLOVITER, BARRY and ROTH, Circuit Judges. Total Pages: 49. Judge: SLOVITER Authoring. Judge Roth dissenting [07-2431, 07-2432]
09/09/2008	JUDGMENT, Reversed and Remanded. Costs taxed against the Appellees. [07-2431, 07-2432]
09/23/2008	PETITION filed by Appellees for Rehearing before Original Panel and Court En Banc, filed. Certificate of Service dated 09/23/2008. [07-2431, 07-2432]
10/17/2008	ORDER (SCIRICA, Chief Judge, SLOVITER, RENDELL, BARRY, AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN and ROTH, Circuit Judges) denying Appellees petition for rehearing, filed. Sloviter, Authoring Judge. Hon. Jane R. Roth, Senior Circuit Judge, as to panel rehearing only. [07-2432, 07-2431]
10/27/2008	MANDATE ISSUED, filed. [07-2431, 07-2432]
	* * * * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Case No. 05-02367
IN RE: MERCK & CO. INC. SECURITIES LITIGATION

DOCKET ENTRIES

DATE	PROCEEDINGS
	* * * * *
06/09/2005	AMENDED COMPLAINT CONSOLIDATED AND FOURTH AMENDED CLASS ACTION COMPLAINT against MERCK & CO, INC., filed by MERCK & CO. INC. SECURITIES LITIGATION IN RE: MDL1658. (Attachments: # 1 Supplement pp. 51-100# 2 Supplement pp. 101-150# 3 Supplement pp. 151-178# 4 Certificate of Service)(BRICKFIELD, PAUL) (Entered: 06/09/2005)
	* * * * *
06/14/2005	AMENDED COMPLAINT (CORRECTED CONSOLIDATED AND FOURTH AMENDED CLASS ACTION COMPLAINT) against all defendants all defendants., filed by

DATE	PROCEEDINGS
	JEROME HABER, STEVEN LEVAN, MARC NATHANSON, RICHARD REYNOLDS. (Attachments: # 1 Supplement pp. 51-100# 2 Supplement 101-150# 3 Supplement 151-178# 4 Certificate of Service)(BRICKFIELD, PAUL) (Entered: 06/14/2005)
	* * * * *
08/12/2005	MOTION to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint by EDWARD SCOLNICK. Responses due by 10/20/2005 (Attachments: # 1 Brief In Support of Motion to Dismiss# 2 Certification of Lawrence M. Rolnick in Support of Motion to Dismiss# 3 Text of Proposed Order # 4 Certificate of Service)(ROLNICK, LAWRENCE) (Entered: 08/12/2005)
08/12/2005	MOTION to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint by MERCK & CO, INC., ALISE S. REICIN, ANNE M. TATLOCK, BERNARD J. KELLEY, CAROLINE DORSA, CELIA COLBERT, DAVID W. ANSTICE, HEIDI G. MILLER, JOHNNETTA B. COLE, JUDY C. LEWENT, KENNETH C. FRAZIER, LAWRENCE A. BOSSIDY, LINDA M. DISTLERATH, LLOYD C. ELAM,

DATE	PROCEEDINGS
	PER G.H. LOFBERG, PER WOLD-OLSEN, PETER S. KIM, RAYMOND V. GILMARTIN, RICHARD C. HENRIQUES, RICHARD T. CLARK, SAMUEL O. THIER, THOMAS E. SHENK, WILLIAM B. HARRISON, WILLIAM G. BOWEN, WILLIAM N. KELLEY. Responses due by 10/20/2005 (Attachments: # 1 Brief in Support of Defendants' Motion to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint (Part 1)# 2 Brief in Support of Defendants' Motion to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint (Part 2)# 3 Affidavit Declaration of Robert H. Baron# 4 Text of Proposed Order # 5 Certificate of Service)(BARON, ROBERT) (Entered: 08/12/2005)
	* * * * *
03/16/2006	BRIEF in Opposition re 13 MOTION to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint, 14 MOTION to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint PLAINTIFFS' OMNIBUS MEMORANDUM OF LAW IN OPPOSITION TO MERCK DEFENDANTS' MOTION TO

DATE	PROCEEDINGS
	DISMISS THE CORRECTED CONSOLIDATED AND FOURTH AMENDED CLASS ACTION COMPLAINT filed by JEROME HABER, STEVEN LEVAN, MARC NATHANSON, RICHARD REYNOLDS. (Attachments: # 1 Brief Part 2# 2 Brief Part 3# 3 Brief Part 4)(BRICKFIELD, PAUL) (Entered: 03/16/2006)
	* * * * *
05/03/2006	REPLY to Response to Motion re 13 MOTION to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint filed by EDWARD SCOLNICK. (Attachments: # 1 Certificate of Service)(ROLNICK, LAWRENCE) (Entered: 05/03/2006)
	* * * * *
05/03/2006	REPLY to Response to Motion re 14 MOTION to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint Reply Memorandum in Further Support of Defendants' Motion to Dismiss filed by MERCK & CO, INC., ALISE S. REICIN, ANNE M. TATLOCK, BERNARD J. KELLEY, CAROLINE DORSA, CELIA COLBERT, DAVID W. ANSTICE, HEIDI G. MILLER,

DATE	PROCEEDINGS
	JOHNNETTA B. COLE, JUDY C. LEWENT, KENNETH C. FRAZIER, LAWRENCE A. BOSSIDY, LINDA M. DISTLERATH, LLOYD C. ELAM, PER G.H. LOFBERG, PER WOLD-OLSEN, PETER S. KIM, RAYMOND V. GILMARTIN, RICHARD C. HENRIQUES, RICHARD T. CLARK, SAMUEL O. THIER, THOMAS E. SHENK, WILLIAM B. HARRISON, WILLIAM G. BOWEN, WILLIAM N. KELLEY. (Attachments: # 1 Affidavit of Robert H. Baron in Further Support of Defendants' Motion to Dismiss Complaint# 2 Exhibit 173 (part 1 of 4) transcript of testimony before US Senate Nov. 18, 2004# 3 Exhibit 173 (part 2 of 4) transcript of testimony before US Senate Nov. 18, 2004# 4 Exhibit 173 (part 3 of 4) transcript of testimony before US Senate Nov. 18, 2004# 5 Exhibit 173 (part 4 of 4) transcript of testimony before US Senate Nov. 18, 2004# 6 Exhibit 174 Kweder statement to US Senate Nov. 18, 2004# 7 Exhibit 175 chart of Defendants' shares and options# 8 Exhibit 176 Gilmartin June 16, 1994 stock option grant# 9 Exhibit 177 Merck 2003 Proxy Statement and Defendants' Forms 4# 10 Exhibit 178 Prospectus of MSIP April 30, 2002# 11

DATE	PROCEEDINGS
	Exhibit 179 Prospectus for MSIP dated June 10, 2004# 12 Certificate of Service) (BARON, ROBERT) (Entered: 05/03/2006)
	* * * * *
03/26/2007	Minute Entry for proceedings held before Judge Stanley R. Chesler : Motion Hearing held on 3/26/2007 re 14 MOTION to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint filed by JUDY C. LEWENT, LINDA M. DISTLERATH, ANNE M. TATLOCK, LAWRENCE A. BOSSIDY, BERNARD J. KELLEY, DAVID W. ANSTICE, WILLIAM G. BOWEN, ALISE S. REICIN, PETER S. KIM, CAROLINE DORSA, RAYMOND V. GILMARTIN, WILLIAM N. KELLEY, CELIA COLBERT, RICHARD T. CLARK, KENNETH C. FRAZIER, WILLIAM B. HARRISON, LLOYD C. ELAM, THOMAS E. SHENK, RICHARD C. HENRIQUES, HEIDI G. MILLER, PER WOLD-OLSEN, MERCK & CO, INC., PER G.H. LOFBERG, JOHNNETTA B. COLE, SAMUEL O. THIER, 162 MOTION to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint filed by NIALL

DATE	PROCEEDINGS
	FITZGERALD, 13 MOTION to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint filed by EDWARD SCOLNICK. DECISION RESERVED 13, DECISION RESERVED 14, DECISION RESERVED 162 (Court Reporter KASHMER.) (tt,) (Entered: 03/27/2007)
	* * * * *
04/12/2007	OPINION. Signed by Judge Stanley R. Chesler on 4/12/07. (jd,) (Entered: 04/13/2007)
04/12/2007	ORDER granting 13 Motion to Dismiss; granting 14 Motion to Dismiss; granting 162 Motion to Dismiss; this complaint is dismissed with prejudice, etc.. Signed by Judge Stanley R. Chesler on 4/12/07. (jd,) (Entered: 04/13/2007)
	* * * * *
03/10/2009	AMENDED COMPLAINT Corrected Fifth Amended Complaint against all defendants all defendants., filed by JEROME HABER, STEVEN LEVAN, RICHARD REYNOLDS, RHODA KANTER, PARK EAST, INC.. (Attachments: # 1 Letter from James E. Cecchi Regarding Corrected Fifth Amended Complaint) (CECCHI,

DATE	PROCEEDINGS
	JAMES) (Entered: 03/10/2009)
	* * * * *
05/01/2009	MOTION to Dismiss the Corrected Consolidated Fifth Amended Class Action Complaint by MERCK & CO., INC., ALISE S. REICIN, ANNE M. TATLOCK, BERNARD J. KELLEY, DAVID W. ANSTICE, HEIDI G. MILLER, JOHNNETTA B. COLE, JUDY C. LEWENT, KENNETH C. FRAZIER, LAWRENCE A. BOSSIDY, NIALL FITZGERALD, PER WOLD-OLSEN, PETER S. KIM, RAYMOND V. GILMARTIN, RICHARD C. HENRIQUES, RICHARD T. CLARK, SAMUEL O. THIER, THOMAS E. SHENK, WILLIAM B. HARRISON, WILLIAM G. BOWEN, WILLIAM N. KELLEY. (Attachments: # 1 Memorandum Of Law In Support Of Defendants' Motion To Dismiss The Corrected Consolidated Fifth Amended Class Action Complaint, # 2 Declaration of Robert H. Baron in Support of the Motion to Dismiss, # 3 Exhibit 1 to Baron Declaration, # 4 Exhibit 2 to Baron Declaration, # 5 Exhibit 3 to Baron Declaration, # 6 Exhibit 4 to Baron Declaration, # 7 Exhibit 5 to Baron Declaration, # 8 Exhibit 6 to Baron Declaration, # 9

DATE	PROCEEDINGS
	Exhibit 7 to Baron Declaration, # 10 Exhibit 8 to Baron Declaration, # 11 Exhibit 9 to Baron Declaration, # 12 Exhibit 10 to Baron Declaration, # 13 Exhibit 11 to Baron Declaration, # 14 Exhibit 12 to Baron Declaration, # 15 Exhibit 13 (part one) to Baron Declaration, # 16 Exhibit 13-2 to Baron Declaration, # 17 Exhibit 13-3 to Baron Declaration, # 18 Exhibit 13-4 to Baron Declaration, # 19 Exhibit 13-5 to Baron Declaration, # 20 Exhibit 13-6 to Baron Declaration, # 21 Exhibit 13-7 to Baron Declaration, # 22 Exhibit 14-1 to Baron Declaration, # 23 Exhibit 14-2 to Baron Declaration, # 24 Exhibit 14-3 to Baron Declaration, # 25 Exhibit 14-4 to Baron Declaration, # 26 Exhibit 14-5 to Baron Declaration, # 27 Exhibit 14-6 to Baron Declaration, # 28 Exhibit 15 to Baron Declaration, # 29 Exhibit 16 to Baron Declaration, # 30 Exhibit 17 to Baron Declaration, # 31 Exhibit 18 to Baron Declaration, # 32 Exhibit 19-1 to Baron Declaration, # 33 Exhibit 19-2 to Baron Declaration, # 34 Exhibit 19-3 to Baron Declaration, # 35 Exhibit 19-4 to Baron Declaration, # 36 Exhibit 20 to Baron Declaration, # 37 Exhibit 21-1 to Baron Declaration, # 38 Exhibit 21-2 to Baron Declaration, # 39 Exhibit 21-3 to Baron Declaration, # 40 Exhibit 21-4 to Baron

DATE	PROCEEDINGS
	Declaration, # 41 Exhibit 22 to Baron Declaration, # 42 Exhibit 23 to Baron Declaration, # 43 Exhibit 24 to Baron Declaration, # 44 Exhibit 25 to Baron Declaration, # 45 Exhibit 26 to Baron Declaration, # 46 Exhibit 27 to Baron Declaration, # 47 Exhibit 28 to Baron Declaration, # 48 Exhibit 29 to Baron Declaration, # 49 Exhibit 30 to Baron Declaration, # 50 Exhibit 31 to Baron Declaration, # 51 Exhibit 32 to Baron Declaration, # 52 Exhibit 33 to Baron Declaration, # 53 Exhibit 34 to Baron Declaration, # 54 Exhibit 35 to Baron Declaration, # 55 Exhibit 36 to Baron Declaration, # 56 Exhibit 37 to Baron Declaration, # 57 Exhibit 38 to Baron Declaration, # 58 Exhibit 39 to Baron Declaration, # 59 Exhibit 40 to Baron Declaration, # 60 Text of Proposed Order, # 61 Certificate of Service)(BARON, ROBERT) (Entered: 05/01/2009)
	* * * * *
05/01/2009	MOTION to Dismiss by EDWARD SCOLNICK. Responses due by 8/3/2009 (Attachments: # 1 Brief Memorandum of Law, # 2 Certification of Sally J. Mulligan, # 3 Text of Proposed Order, # 4 Certificate of Service)(MULLIGAN, SALLY)

DATE	PROCEEDINGS
	(Entered: 05/01/2009)
	* * * * *
07/07/2009	STIPULATION AND ORDER that the proceedings in this Court shall be stayed pending the adjudication of the Supreme Court Appeal currently before the Supreme Court; parties shall jointly report to the Court within 30 days following completion of proceedings before the Supreme Court, etc.. Signed by Judge Stanley R. Chesler on 7/7/09. (jd,) (Entered: 07/07/2009)

RELEASED FOR PUBLICATION

DOCKET NO. 1658

BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE MERCK & CO., INC., SECURITIES, DERIVATIVE & "ERISA" LITIGATION

BEFORE WM. TERRELL HODGES, CHAIRMAN, JOHN F. KEENAN, D. LOWELL JENSEN, J. FREDERICK MOTZ, ROBERT L. MILLER, JR., KATHRYN H. VRATIL AND DAVID R. HANSEN, JUDGES OF THE PANEL*

Filed: February 23, 2005

TRANSFER ORDER

This litigation presently consists of fourteen actions listed on the attached Schedule A as follows: eight actions in the Eastern District of Louisiana and six actions in the District of New Jersey. Before the Panel are two motions seeking centralization, pursuant to 29 U.S.C. § 1407, of all — or a subset — of these actions in a single federal district. Plaintiff in one New Jersey action seeks centralization of the Employee Retirement Income Security Act (ERISA) actions in the District of New Jersey. Merck & Co., Inc. (Merck) initially moved to centralize all actions in the New Jersey district;[1]

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* Judge Motz took no part in the decision of this matter.

[1] The New Jersey moving plaintiff sought 1407 centralization of three ERISA actions: two actions in the Eastern District of

responding Merck affiliated officer and director defendants agree that centralization there is appropriate. Various plaintiffs support centralization of all actions in one federal district or separate centralization of the ERISA or securities actions in either the New Jersey district or the Eastern District of Louisiana.

On the basis of the papers filed and hearing session held, the Panel finds that the actions in this litigation involve common questions of fact and that centralization in the District of New Jersey will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. All actions share factual questions arising from allegations that Merck misrepresented and/or concealed the safety risks of Vioxx and that this conduct affected Merck's financial condition. Whether the actions be brought by securities holders seeking relief under the federal securities laws, shareholders suing derivatively on behalf of Merck, or

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Louisiana and one action in the District of New Jersey. Merck's Section 1407 motion added sixteen additional actions: five ERISA and three securities actions in the District of New Jersey; four securities and two derivative actions in the Eastern District of Louisiana; and one securities action each in the Eastern and Western Districts of Pennsylvania. The three New Jersey securities actions and the two Pennsylvania securities actions have recently been voluntarily dismissed. Accordingly, the question of inclusion of these five actions in Section 1407 proceedings is moot.

The panel has been informed that additional potentially related actions have recently been filed as follows: ten actions in the Eastern District of Louisiana, six actions in the District of New Jersey and one action in the Central District of Illinois. These actions and any other related actions will be treated as potential tag-along actions. *See* Rules 7.4 and 7.5, R.P.J.P.M.L., 199 F.R.D. 425, 435-36 (2001).

participants in Merck retirement savings plans suing for ERISA violations, all actions can be expected to focus on a significant number of common events, defendants, and/or witnesses. Centralization under Section 1407 is necessary in order to eliminate duplicative discovery, prevent inconsistent pretrial rulings (especially with respect to questions of class certification), and conserve the resources of the parties, their counsel and the judiciary. *See In re Enron Corp. Securities, Derivative & "ERISA" Litigation*, 196 F.Supp.2d 1375 (J.P.M.L. 2002).

While either the District of New Jersey or the Eastern District of Louisiana would have been an appropriate choice as transferee district for this docket, the Panel has selected the District of New Jersey, because i) documents and witnesses will likely be located there at Merck's New Jersey headquarters, and ii) the New Jersey district is relatively conveniently located for the parties and witnesses taken as a whole.

IT IS THEREFORE ORDERED that, pursuant to 28 U.S.C. § 1407, the actions listed on Schedule A and pending outside the District of New Jersey are transferred to the District of New Jersey and, with the consent of that court, assigned to the Honorable Stanley R. Chesler for coordinated or consolidated pretrial proceedings with the actions listed on Schedule A and pending there.

FOR THE PANEL:

WM. TERRELL HODGES
CHAIRMAN

SCHEDULE A

MDL-1658 — In re Merck & Co., Inc., Securities, Derivative & "ERISA" Litigation

Eastern District of Louisiana

Frank Pringle, et al. v. Merck & Co., Inc., et al., C.A. No. 2:03-3125

Ruth Ravnitsky, et al. v. Merck & Co., Inc., et al., C.A. No. 2:04-147

Isaac Reiner, et al. v. Merck & Co., Inc., et al., C.A. No. 2:04-222

Gail Lynn Stark, et al. v. Merck & Co., Inc., et al., C.A. No. 2:04-406

Doris Staehr, etc. v. Raymond V. Gilmartin, et al., C.A. No. 2:04-721

Halpert Enterprises, Inc., etc. v. Raymond Gilmartin, et al., C.A. No. 2:04-758

Vincent P. Mullet, etc. v. Merck & Co., Inc., et al., C.A. No. 2:04-2716

Denise Burtoft v. Merck & Co., Inc., et al., C.A. No. 2:04-2762

District of New Jersey

Robert Mortensen v. Merck & Co., Inc., et al., C.A. No. 3:04-4951

Robert Cimato, etc. v. Merck & Co., Inc., et al., C.A. No. 3:04-4987

Henry Douglas Horne, Jr., etc. v. Merck Co., Inc., et al., C.A. No. 3:04-5156

Darrell W. Nelson v. Merck & Co., Inc., et al., C.A. No. 3:04-5260

Zeph Ugwuneri v. Merck & Co., Inc., et al., C.A. No. 3:04-5397

Andrew S. Zonay v. Merck & Co., Inc., et al., C.A. No. 3:04-5435

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MDL No. 1658 (SRC)
Case No. 3:05-CV-01151-SRC-TJB
Case No. 3:05-CV-02367-SRC-TJB

IN RE MERCK & CO., INC., SECURITIES DERIVATIVE & "ERISA" LITIGATION

THIS DOCUMENT RELATES TO THE CONSOLIDATED SECURITIES ACTION

CORRECTED CONSOLIDATED AND FOURTH AMENDED CLASS ACTION COMPLAINT

PRELIMINARY STATEMENT

1. Plaintiffs, on behalf of themselves and the Class they seek to represent (defined below), for this Corrected Consolidated and Fourth Amended Class Action Complaint, make the following allegations against Defendants based upon the investigation conducted by and under the supervision of their counsel, which included, among other things:

i. interviews of former employees of Merck & Co., Inc. ("Merck" or the "Company") and other persons with knowledge and information with respect to the matters alleged herein;

ii. review and analysis of the public filings of Merck and the other Defendants, including their filings with the Securities and Exchange Commission (the "SEC");

iii. review and analysis of press releases, reports to shareholders, and other public statements issued by Defendants;

iv. review and analysis of news articles and media reports relating to the matters alleged herein;

v. review and analysis of analyst reports relating to Merck;

vi. review and analysis of securities analyst conference call transcripts;

vii. review and analysis of documents and information obtained by Plaintiffs from the United States Department of Health and Human Services pursuant to the Freedom of Information Act;

viii. review and analysis of pertinent scientific and medical literature;

ix. review and analysis of pertinent documents issued by the United States Food and Drug Administration (the "FDA"), including official communications between the FDA and Merck;

x. consultations with experts;

xi. review and analysis of Congressional testimony and materials issued by the United States Congress;

xii. review and analysis of internal Merck documents that are in the public domain;

xiii. review and analysis of advertising and promotional materials that Defendants disseminated during the Class Period concerning VIOXX;

xiv. review and analysis of VIOXX label leaflets; and

xv. review and analysis of pleadings in other actions filed against Merck that arise out of the same core issues and facts alleged herein concerning VIOXX.

2. Except as alleged herein, the underlying information relating to Defendants' misconduct and the particulars thereof, including millions of pages of documents produced in the VIOXX personal injury cases currently designated as confidential, as well as tens of thousands of pages of documents produced to United States government investigatory agencies and bodies, is not available to Plaintiffs and the public, and lies within the possession and control of Defendants and other Merck insiders.

3. Based, among other things, on statements made by Defendants themselves, investigations commenced by multiple United States government agencies, Congressional hearings, and thousands of other actions filed against Merck that arise from Defendants' misstatements and failures to disclose the health risks of VIOXX, Plaintiffs believe that substantial additional evidentiary support will exist to prove the allegations set forth herein after a reasonable opportunity for discovery. As events continue to unfold day to day, more and more documents and information that further support Plaintiffs' claims alleged herein enter the public domain.

CONFIDENTIAL SOURCES

4. Confidential sources who provided information for Plaintiffs' counsel's investigation include former Merck employees who worked at the Company during the relevant time period and dealt directly with VIOXX and other persons who have knowledge and information with respect to matters referred to herein. The sources include the following:

(a) Former Merck Employee ("FME")-1 was a Merck sales representative from approximately April 1998 through November 2003, and sold VIOXX during the Class Period.

(b) FME-2 was a Merck sales representative from approximately June 2, 2002 through April 2003, and sold VIOXX during the Class Period.

(c) FME-3 was a Merck sales representative from approximately September 11, 2000 through September 21, 2003, who dealt with specialists and primary care physicians.

(d) FME-4 was a Merck sales representative from approximately May 1999 through June 2002, and sold VIOXX during the Class Period.

(e) FME-5 was a Merck sales representative from approximately 1980 through February 2003, and sold VIOXX during the Class Period.

(f) FME-6 was a Merck sales representative from approximately June 2000 through July 2003, and sold VIOXX during the Class Period.

(g) FME-7 was a Merck sales manager who worked at the Company from approximately April 1999 through May 2004, and who was involved with VIOXX

during the Class Period. FME-7 worked in Merck's National Service Center (the "Service Center"), which tracked information about drugs developed by the Company's competitors. The Service Center also served as "an information providing tool" for Merck sales representatives. In addition, Merck employees who worked in the Service Center prepared reports for senior level Merck officials concerning, among other things, VIOXX.

(h) FME-8 was a Merck clinical researcher who was a major participant in the VIGOR Study, which is discussed below.

NATURE OF THE ACTION

5. This is a class action on behalf of the purchasers of Merck securities between May 21, 1999 and October 29, 2004, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act"). Plaintiffs also seek to pursue remedies under the Securities Act of 1933 (the "Securities Act") on behalf of Class members who purchased Merck common stock through the Merck Stock Investment Plan (the "MSIP"), pursuant to Merck's Registration Statement dated April 26, 2002 (the "Registration Statement") and the prospectuses for the MSIP dated April 26, 2002, April 30, 2002 (the "April 30, 2002 Prospectus"), and June 10, 2004 (the "June 10, 2004 Prospectus").

6. During the Class Period, Defendants made a series of materially false and misleading statements and omissions concerning, among other things, the safety profile of Merck's prescription painkilling drug VIOXX, generically known as rofecoxib. Defendants concealed

from the market that patients taking VIOXX, which Defendants and the market touted as Merck's "savior" when it was introduced in 1999, had a significantly increased risk of having a heart attack or other cardiovascular event. ***A study led by an FDA official projects that the widespread use of VIOXX may have led to as many as 139,000 heart attacks and cardiac events, 30% to 40% of which resulted in death.***

7. Merck describes itself as a global research-focused pharmaceutical products company, which discovers, develops, manufactures, and markets a broad range of products to improve human and animal health, directly and through its joint ventures. On May 21, 1999, VIOXX was approved by the FDA for treating primary dysmenorrheal (severe menstrual cramps), managing acute pain in adults, and relieving symptoms relating to osteoarthritis. During the Class Period, ***VIOXX was Merck's second best selling drug***.

8. In May 1999, Merck began vigorously marketing VIOXX to health professionals in the United States by conducting audio conferences, making sales presentations, and issuing press releases, and continued to do so throughout the Class Period. Defendants' consistent representations that VIOXX possessed all of the beneficial effects of traditional nonsteroidal anti-inflammatory drugs ("NSAIDs"), such as aspirin, ibuprofen, and naproxen, without causing serious gastrointestinal ("GI") side effects, led investors to believe VIOXX would be a "blockbuster" drug for Merck.

9. However, unbeknownst to the public, by at least May 1999, Defendants were fully aware — through, among other things, clinical studies Defendants were conducting with respect to VIOXX, as well as through

the FDA's Adverse Event Reporting System, which collects information concerning adverse events associated with VIOXX, including cardiovascular events — that their public statements concerning the safety profile of VIOXX, and its commercial viability and ability to continue generating substantial revenues over the life of Merck's patent were materially false and misleading, and that VIOXX caused a statistically significant increase in cardiovascular events. Nevertheless, Defendants continued to promote VIOXX as being significantly safer than the class of NSAIDs, as well as other analgesic and anti-inflammatory therapies available for the management of pain. Because (i) VIOXX is no more effective in treating inflammation and pain than traditional NSAIDs and (ii) traditional NSAIDs were sold to consumers at a fraction of the cost of VIOXX, the perception that VIOXX's safety profile was superior to traditional NSAIDs was critical to the drug's success and to investors' assessment of Merck's prospects.

10. Thus, throughout the Class Period, Defendants misrepresented the safety profile of VIOXX, including concealing and minimizing the significantly increased risk of heart attacks in patients taking the drug. As part of Defendants' scheme to conceal the serious cardiovascular risks associated with VIOXX, Defendants trained the Company's sales representatives to misrepresent the safety of VIOXX.

11. Defendants were motivated to protect sales of VIOXX, the Company's new "blockbuster drug," in part because Merck was facing the expiration of patent on a number of its most profitable drugs. ***Every month*** Defendants were able to keep VIOXX on the market by concealing the truth allowed Merck to realize ***tens of***

millions of dollars in revenues. In addition, Defendants' misrepresentations enabled Company insiders to profit personally ***by selling almost 2.6 million shares of Merck stock for more than $265 million in proceeds.***

12. Defendants' materially false misrepresentations and omissions artificially inflated the trading price of Merck common stock to a Class Period high of almost $95. Merck stock now trades below $32.

13. During the Class Period, Defendants flatly rejected, or mischaracterized any report that suggested that there were cardiovascular risks posed by VIOXX. In at least one instance, Defendants took affirmative steps to dissuade the authors of a prospective article that reported an increased risk of adverse cardiovascular events in patients taking VIOXX from publishing the article.

14. Ultimately, Defendants were forced to withdraw VIOXX from the worldwide market. Thereafter, the public disclosure of internal Company documents made clear that Defendants not only were aware of the serious cardiovascular risks associated with VIOXX, but also had engaged in a willful scheme to suppress the truth through a pattern of deception and intimidation. Dr. David Graham, Associate Director for Science and Medicine in the FDA's Office of Drug Safety, who testified on November 18, 2004 before the Senate Committee on Finance, referred to Defendants' scheme as "the single greatest drug catastrophe in the history of the world." As the truth became known, the trading price of Merck common stock plummeted. In fact, between the worldwide withdrawal of VIOXX on September 30, 2004, and the public confirmation of Defendants' awareness and cover-up of the serious, life-

threatening risks posed by VIOXX on November 1, 2004, Merck's market capitalization fell by ***more than $37.2 billion***.

15. [TEXT INTENTIONALLY OMITTED]

16. On September 30, 2004, Defendants shocked the world by announcing that Merck was immediately withdrawing VIOXX from world markets after an independent data safety monitoring board, which had overseen a long-term study of VIOXX, recommended the study be halted because of an increased risk of serious cardiovascular events among members of the study group. The announcement was in stark contrast to Defendants' prior representations that assured the market about VIOXX's safety, as well as Defendants' efforts to suppress medical and scientific information that showed VIOXX is associated with significant and dangerous cardiovascular risks.

JURISDICTION AND VENUE

17. The claims asserted herein arise under and pursuant to §§ 11, 12(a)(2), and 15 of the Securities Act [15 U.S.C. §§ 77k, 77l(a)(2), and 77o], and under and pursuant to §§ 10(b), 20(a), and 20(A) of the Exchange Act [15 U.S.C. §§ 78j(b), 78t(a), 78t-1(a)] and Rule 10b-5 promulgated thereunder by the SEC.

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, § 22 of the Securities Act [15 U.S.C. § 77v], and § 27 of the Exchange Act [15 U.S.C. § 78aa.]

19. Venue is proper in this District pursuant to § 27 of the Exchange Act, § 22 of the Securities Act, and 28 U.S.C. § 1391(b). In addition, venue is proper in this

District pursuant to the Order of the Judicial Panel on Multidistrict Litigation, dated February 23, 2005.

20. In connection with the acts and transactions alleged in this Complaint, Defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mails, interstate telephone communications, the Internet, and the facilities of the national securities markets.

PARTIES

Plaintiffs

21. Court-appointed Lead Plaintiffs Richard Reynolds, Steven LeVan, Marc Nathanson, and Jerome Haber purchased Merck common stock at artificially inflated prices during the Class Period and have been damaged by Defendants' wrongful conduct. The Lead Plaintiffs previously submitted certifications reflecting their transactions in Merck common stock during the Class Period, which are incorporated by reference herein.

22. Plaintiff Union Asset Management Holding AG ("Union"), on behalf of its funds, UniSector; BioPharma; Uni21.Jahrhundert-net-; UniGlobalTitans 50; UniGlobal; UniGlobal-net- and UniSector: High Tech (the "Funds"), purchased Merck common stock during the Class Period at artificially inflated prices and has been damaged by Defendants' wrongful conduct. Union is a fund management company headquartered in Frankfurt am Main, Germany. Union controls and manages and is attorney-in-fact for each of the Funds. Plaintiff Union previously submitted a certification

reflecting the Funds' transactions in Merck common stock during the Class Period, which is incorporated by reference herein.

23. Plaintiffs Loren Arnoff, Robert Edwin Burns, Jan Charles Finance S.A., Martin Mason, Frank H. Saccone, Charlotte Savarese, Joe Savarese, Joseph Goldman, Sherrie B. Knuth, Joseph S. Fisher, M.D., and Naomi Raphael purchased Merck common stock during the Class Period at artificially inflated prices and have been damaged by Defendants' wrongful conduct. The aforementioned Plaintiffs previously submitted certifications reflecting their transactions in Merck common stock during the Class Period, which are incorporated by reference herein.

24. Plaintiffs Rhoda Kanter and Park East, Inc. ("Park East"), purchased shares of Merck common stock through MSIP. Those shares were sold by Merck pursuant to a shelf registration which became effective on April 26, 2002. The MSIP, which was instituted in 1997, is a dividend reinvestment program that permits Merck shareholders automatically to reinvest cash dividends paid on Merck common stock towards the purchase of additional shares of Merck common stock. Plaintiffs Kanter and Park East previously submitted certifications reflecting their transactions in Merck common stock during the Class Period, which are incorporated by reference herein.

Defendants

25. Defendant Merck is a global pharmaceutical company that develops, manufactures, and markets a broad range of human and animal health products. As of September 30, 2004, the Company had approximately 2.2

billion shares of common stock outstanding, which were actively and efficiently traded on the New York Stock Exchange (the "NYSE"). Merck is a New Jersey corporation with its principal place of business located at One Merck Drive, Whitehouse Station, New Jersey.

26. (a) Defendant Raymond V. Gilmartin ("Gilmartin") was, during the Class Period, Merck's Chairman, President, and Chief Executive Officer. Defendant Gilmartin became Merck's Chairman in November 1994. Gilmartin was, at all relevant times, also a member of the Company's Management Committee. According to Merck, the Board of Directors and the Management Committee are responsible for the Company's objectives and policies, and the stewardship of Merck's resources. On May 6, 2005, approximately seven months after Merck withdrew VIOXX from the market, and ten months before his previously scheduled retirement, defendant Gilmartin was replaced as the Company's Chairman, President, and Chief Executive Officer by Richard Clark, who had been in charge of the Company's manufacturing operations.

(b) As detailed herein, during the Class Period, defendant Gilmartin was Merck's most senior spokesperson, and he made public statements concerning VIOXX and Merck's financial condition, performance, and prospects that were materially false and misleading and omitted to state material facts. Defendant Gilmartin signed at least the following documents that the Company filed with the SEC during the Class Period: the 1999 Form 10-K; the 2000 Form 10-K; the 2001 Form 10-K; the Registration Statement; the second quarter 2002 Form 10-Q; the third quarter 2002 Form 10-Q; the 2002 Form 10-K; the first quarter 2003 Form 10-Q; the second quarter 2003 Form 10-Q;

the third quarter 2003 Form 10-Q; the first quarter 2004 Form 10-Q; the 2003 Form 10-K; and the second quarter 2004 Form 10-Q. After the Sarbanes-Oxley Act of 2002 became effective in July 2002, defendant Gilmartin, pursuant to §302 of the Act, also signed certifications that were attached to Merck's Form 10-Ks and Form 10-Qs filed with the SEC.

(c) As detailed herein, defendant Gilmartin was a direct, substantial, and primary participant in the misconduct alleged herein. While in possession of materially adverse non-public information regarding Merck, defendant Gilmartin personally profited from the sale of Merck stock at artificially inflated prices during the Class Period. During the Class Period, defendant Gilmartin sold 639,200 shares of Merck stock from his personal holdings, or 52% of his personal holdings, realizing more than $30.3 million in proceeds. In addition, defendant Gilmartin received substantial performance-based bonuses and other compensation based on, among other things, changes in Merck's earnings per share and sales compared to Merck's competitors.

27. (a) Defendant Edward Scolnick ("Scolnick") was Merck's Executive Vice President for Science and Technology and President for Merck Research Laboratories from the beginning of the Class Period through and including December 31, 2002, when he retired. During 1999, 2000, and 2001, defendant Scolnick was also a member of the Company's Management Committee. As the officer in charge of research and development, defendant Scolnick was intimately involved and fully conversant with the development, research, and testing of VIOXX, and was well aware of the risks and problems associated with the drug. Following his

retirement, from January 1, 2003 through the end of the Class Period, Scolnick served as President Emeritus, Merck Research Laboratories.

(b) As detailed herein, during the Class Period, defendant Scolnick was one of Merck's chief spokespersons in connection with information provided to the public about VIOXX and he made public statements concerning VIOXX and Merck's financial condition, performance and prospects that were materially false and misleading and omitted to state material facts. Defendant Scolnick signed at least the following documents filed with the SEC during the Class Period, all of which contained materially false and misleading statements and omitted to state material facts: the 1999 Form 10-K; the 2000 Form 10-K; the 2001 Form 10-K; and the Registration Statement.

(c) As detailed herein, defendant Scolnick was a direct, substantial, and primary participant in the wrongdoing alleged herein. While in possession of materially adverse non-public information regarding Merck, defendant Scolnick personally profited from the sale of Merck securities at artificially inflated prices during the Class Period. During the Class Period, Scolnick sold, at the very least, 381,200 shares of Merck stock from his personal holdings, or approximately 61% of his personal holdings, recognizing more than $32.4 million in proceeds. In addition, defendant Scolnick received substantial performance-based bonuses and other compensation based on, among other things, changes in Merck's earnings per share and sales compared to Merck's competitors. Due to the fact that defendant Scolnick retired from the Company on January 1, 2003, he was no longer subject to public reporting requirements concerning the sale of Merck

stock. Without the benefit of discovery, Plaintiffs are unable to ascertain whether defendant Scolnick sold any additional shares of Merck common stock during the Class Period.

28. (a) Defendant Kenneth C. Frazier ("Frazier") has been Merck's Senior Vice President and General Counsel since December 1999. As General Counsel, defendant Frazier is responsible for legal and public affairs functions for the Company. Defendant Frazier was, at all relevant times, also a member of the Company's Management Committee.

(b) As detailed herein, defendant Frazier made public statements concerning VIOXX and Merck's financial condition, performance, and prospects that were materially false and misleading and omitted to state material facts. Defendant Frazier signed at least the following documents that the Company filed with the SEC during the Class Period: the first quarter 2000 Form 10-Q; the second quarter 2000 form 10-Q; the third quarter 2000 Form 10-Q; the first quarter 2001 Form 10-Q; the second quarter 2001 Form 10-Q; the third quarter 2001 Form 10-Q; the first quarter 2002 Form 10-Q; the second quarter 2002 Form 10-Q; the third quarter 2002 Form 10-Q; the first quarter 2003 Form 10-Q; the second quarter 2003 Form 10-Q; the third quarter 2003 Form 10-Q; and the second quarter 2004 Form 10-Q.

(c) As detailed herein, defendant Frazier was a direct, substantial, and primary participant in the misconduct alleged herein. While in possession of materially adverse non-public information regarding Merck, defendant Frazier personally profited from the sale of Merck stock at artificially inflated prices during the Class Period. During the Class Period, Frazier sold 38,960 shares of Merck stock from his personal holdings,

or approximately 76% of his personal holdings, recognizing more than $1.9 million in proceeds.

29. (a) Defendant Richard C. Henriques ("Henriques") was, at all relevant times, Merck's Vice President and Controller, and was responsible for the Corporate Controller's Group and for providing financial support for Merck's Human Health operations in various parts of the world, including the United States.

(b) As detailed herein, during the Class Period, defendant Henriques was Merck's chief accounting officer, and he made or endorsed public statements concerning VIOXX and Merck's financial condition, performance, and prospects that were materially false and misleading and omitted to state material facts. Defendant Henriques signed at least the following documents that the Company filed with the SEC during the Class Period: the third quarter 1999 Form 10-Q; the 1999 Form 10-K; the first quarter 2000 Form 10-Q; the second quarter 2000 Form 10-Q; the third quarter 2000 Form 10-Q; the 2000 Form 10-K; the first quarter 2001 Form 10-Q; the second quarter 2001 Form 10-Q; the third quarter 2001 Form 10-Q; the 2001 Form 10-K; the first quarter 2002 Form 10-Q; the Registration Statement; the second quarter 2002 Form 10-Q; the third quarter 2002 Form 10-Q; the 2002 Form 10-K; the first quarter 2003 Form 10-Q; the second quarter 2003 Form 10-Q; the third quarter 2003 form 10-Q; the 2003 Form 10-K; the first quarter 2004 Form 10-Q; and the second quarter 2004 Form 10-Q.

(c) As detailed herein, defendant Henriques was a direct, substantial, and primary participant in the wrongdoing alleged herein. While in possession of material adverse information regarding Merck, defendant Henriques personally profited from the sale of

Merck securities at artificially inflated prices during the Class Period. During the Class Period, Henriques sold 33,500 shares of Merck stock from his personal holdings, or approximately 94% of his personal holdings, recognizing more than $1.8 million in proceeds.

30. (a) Defendant Peter S. Kim ("Kim") joined the Company and became an executive officer in February 2001. He succeeded defendant Scolnick as President for Merck Research Laboratories on January 1, 2003, and held that position through the end of the Class Period. As President for Merck Research Laboratories, defendant Kim reported directly to defendant Gilmartin, and was responsible for all of Merck's internal drug-discovery development activities, and external scientific initiatives.

(b) As detailed herein, during the Class Period, defendant Kim was one of Merck's chief spokespersons in connection with information provided to the public about VIOXX and he made public statements concerning VIOXX and Merck's financial condition, performance, and prospects that were materially false and misleading and omitted to state material facts.

(c) As detailed herein, defendant Kim was a direct, substantial, and primary participant in the wrongdoing alleged herein. According to Merck's Class Period SEC filings, defendant Kim received substantial performance-based bonuses and other compensation based on, among other things, changes in Merck's earnings per share and sales compared to Merck's competitors during the Class Period. Without the benefit of discovery, Plaintiffs are unable to determine whether defendant Kim, while in possession of material adverse information regarding Merck, profited from the

sale of Merck securities at artificially inflated prices during the Class Period.

31. (a) Defendant Judy C. Lewent ("Lewent") was, at all relevant times, Merck's Senior Vice President and Chief Financial Officer, and was responsible for financial and corporate development functions, internal auditing, and the Company's joint venture relationships. She has been the Company's Chief Financial Officer since 1990. Defendant Lewent was, at all relevant times, also a member of the Company's Management Committee.

(b) As detailed herein, defendant Lewent made public statements concerning VIOXX and Merck's financial condition, performance, and prospects that were materially false and misleading and omitted to state material facts. Defendant Lewent signed at least the following documents that the Company filed with the SEC during the Class Period: the 1999 Form 10-K; the 2000 Form 10-K; the 2001 Form 10-K; the Registration Statement; the second quarter 2002 Form 10-Q; the third quarter 2002 Form 10-Q; the 2002 Form 10-K; the first quarter 2003 Form 10-Q; the second quarter 2003 Form 10-Q; the third quarter 2003 Form 10-Q; the 2003 Form 10-K; the first quarter 2004 Form 10-Q; the 2003 Form 10-K; and the second quarter 2004 Form 10-Q. After the Sarbanes-Oxley Act of 2002 became effective in July 2002, defendant Lewent, pursuant to §302 of the Act, also signed certifications that were attached to Merck's Form 10-Ks and Form 10-Qs filed with the SEC.

(c) As detailed herein, defendant Lewent was a direct, substantial, and primary participant in the wrongdoing alleged herein. While in possession of material adverse information regarding Merck,

defendant Lewent personally profited from the sale of Merck securities at artificially inflated prices during the Class Period. According to Merck's Class Period SEC filings, defendant Lewent received substantial performance-based bonuses and other compensation based on, among other things, changes in Merck's earnings per share and sales compared to Merck's competitors. During the Class Period, defendant Lewent sold 267,200 shares of Merck stock from her personal holdings, or approximately 52% of her personal holdings, recognizing more than $16.5 million in proceeds.

32. (a) Defendant Alise S. Reicin ("Reicin") was, at all relevant times, the Executive Director of Clinical Research at Merck Research Laboratories. Defendant Reicin was responsible for overseeing research with regard to the safety and efficacy of Merck products, including VIOXX, and supervised the VIGOR Study.

(b) As detailed herein, defendant Reicin was a direct, substantial, and primary participant in the wrongdoing. As detailed herein, during the Class Period, defendant Reicin made public statements concerning VIOXX that were materially false and misleading and omitted to state material facts.

(c) As defendant Reicin was not required to file information with the SEC concerning her transactions in Merck securities during the Class Period, without the benefit of discovery, Plaintiffs are unable to determine whether defendant Reicin, while in possession of material adverse information regarding Merck, profited from the sale of Merck securities at artificially inflated prices.

33. Defendants Gilmartin, Scolnick, Frazier, Henriques, Lewent, Kim, and Reicin are collectively referred to herein as the "Individual Defendants." Defendant Merck and the Individual Defendants are collectively referred to herein as the "Defendants."

34. The Individual Defendants, because of their positions of control and authority as senior executive officers and directors of the Company, had access to the adverse undisclosed information about its business, operations, products, performance, and prospects through their access to internal corporate documents and information (including documents and information concerning VIOXX), conversations and associations with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof, and reports and other information provided to them in connection therewith.

35. The Individual Defendants participated in drafting, preparing, and/or approving the public reports and other statements and communications complained of herein, and were aware of, or recklessly disregarded, the material misstatements contained therein, and omissions therefrom, and were aware of their materially false and misleading nature.

36. The Individual Defendants, as senior executive officers and directors of the Company, were able to and did control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. The Individual Defendants were provided with copies of the documents and statements alleged herein to be materially false and misleading prior to or shortly after their issuance, or had the ability and opportunity to prevent their issuance or cause them to be withdrawn or

corrected. As specified herein, the Company's SEC filings complained of herein were signed by the Individual Defendants, and after July 2002 included certifications by defendants Gilmartin and Lewent pursuant to §302 of the Sarbanes-Oxley Act of 2002. Accordingly, the Individual Defendants are responsible for the accuracy of the public reports, filings, releases, and other statements detailed herein and are primarily liable for the misrepresentations and omissions contained therein.

37. As senior officers and controlling persons of a publicly-held company whose securities were, during the relevant time, registered with the SEC pursuant to the federal securities laws, traded on the NYSE, and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to disseminate promptly accurate and truthful information with respect to the Company's performance, operations, business, products, and prospects, and to withdraw or correct any previously issued statements that were or had become materially misleading or untrue, so that the public had access to true and correct information, and the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants' wrongdoing during the Class Period violated these specific requirements and obligations. Under rules and regulations promulgated by the SEC, including Item 303 of Regulation S-K, the Individual Defendants also had a duty to report, among other things, all trends and uncertainties that were reasonably likely to affect Merck's net sales, revenues, or income. The Individual Defendants' wrongdoing during the Class Period, as alleged herein, also violated this specific requirement and obligation.

38. Each of the Individual Defendants is liable as a primary participant in a wrongful scheme and course of business that operated as a fraud and deceit on purchasers of Merck securities during the Class Period, which included the dissemination of materially false and misleading statements and concealment of material adverse facts. The scheme: (i) deceived the investing public regarding Merck's business, operations, performance, products, and prospects, and the true value of Merck securities; and (ii) caused Plaintiffs and other members of the Class to purchase Merck securities at artificially inflated prices, which fell as the truth concerning VIOXX, including its safety, commercial viability, and ability to generate substantial revenues over the life of Merck's patent, ultimately became known.

39. In making the statements complained of herein, the Individual Defendants, who were all senior officers and controlling persons of Merck, were acting on behalf of the Company in the regular course of business. Therefore, each of the statements made by the Individual Defendants is attributable to the Company.

40. The Individual Defendants are liable for the materially false and misleading statements pleaded herein that were issued by or in the name of the Company, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants, each of whom was intimately involved in the day-to-day operations of Merck. The Individual Defendants acted with respect to the wrongdoing alleged herein as a group, and the public filings, press releases, and other public statements complained of herein, were the product of the collective actions of the narrowly defined group of Individual

Defendants. The Individual Defendants, by virtue of their high-level positions within Merck, directly and actively participated in the management and day-to-day operations of the Company, and were privy to confidential non-public information concerning the business, operations, performance, products, and prospects of Merck. In addition, the Individual Defendants were involved in drafting, reviewing, approving, and/or disseminating the materially false and misleading statements issued by Merck and approved or ratified those statements, and, therefore, adopted them as their own.

41. Defendant Lawrence A. Bossidy ("Bossidy"), at all times relevant hereto, served as a director of Merck. Defendant Bossidy signed, among other things, the Registration Statement, which the Company filed with the SEC, and which contained materially false and misleading statements and omitted to state material facts.

42. Defendant William G. Bowen ("Bowen"), at all times relevant hereto, served as a director of Merck. Defendant Bowen signed, among other things, the Registration Statement, which the Company filed with the SEC, and which contained materially false and misleading statements and omitted to state material facts.

43. Defendant Johnnetta B. Cole ("Cole"), at all times relevant hereto, served as a director of Merck. Defendant Cole signed, among other things, the Registration Statement, which the Company filed with the SEC, and which contained materially false and misleading statements and omitted to state material facts.

44. Defendant Niall FitzGerald ("FitzGerald"), at all times relevant hereto, served as a director of Merck. Defendant FitzGerald signed, among other things, the Registration Statement, which the Company filed with the SEC, and which contained materially false and misleading statements and omitted to state material facts.

45. Defendant William B. Harrison ("Harrison"), at all times relevant hereto, served as a director of Merck. Defendant Harrison signed, among other things, the Registration Statement, which the Company filed with the SEC, and which contained materially false and misleading statements and omitted to state material facts.

46. Defendant William N. Kelley ("W. Kelley"), at all times relevant hereto, served as a director of Merck. Defendant W. Kelley signed, among other things, the Registration Statement, which the Company filed with the SEC, and which contained materially false and misleading statements and omitted to state material facts.

47. Defendant Heidi G. Miller ("Miller"), at all times relevant hereto, served as a director of Merck. Defendant Miller signed, among other things, the Registration Statement, which the Company filed with the SEC, and which contained materially false and misleading statements and omitted to state material facts.

48. Defendant Thomas E. Shenk ("Shenk"), at all times relevant hereto, served as a director of Merck. Defendant Shenk signed, among other things, the Registration Statement, which the Company filed with the SEC, and which contained materially false and

misleading statements and omitted to state material facts.

49. Defendant Anne M. Tatlock ("Tatlock"), at all times relevant hereto, served as a director of Merck. Defendant Tatlock signed, among other things, the Registration Statement, which the Company filed with the SEC, and which contained materially false and misleading statements and omitted to state material facts.

50. Defendant Samuel O. Thier ("Thier"), at all times relevant hereto, served as a director of Merck. Defendant Thier signed, among other things, the Registration Statement, which the Company filed with the SEC, and which contained materially false and misleading statements and omitted to state material facts.

51. Defendants Gilmartin, Lewent, Henriques, Bossidy, Bowen, Cole, FitzGerald, Harrison, W. Kelley, Miller, Scolnick, Shenk, Tatlock, and Thier are collectively referred to herein as the "Director Defendants."

52. Defendant David Anstice ("Anstice") was, at all relevant times, President of Merck's Human Health Prescription Division, during all relevant times, which reasonably would have made him privy to information regarding the safety of VIOXX and its results.

53. Defendant Richard T. Clark ("Clark") was President of Medco Health, then a wholly-owned subsidiary of Merck, from January 2000 through December 2002; President and CEO of Medco Health Solutions, Inc. from January 2003 through May 2003; and President of Merck Manufacturing Division from June 2003 through the Class Period, which reasonably

would have made him privy to information regarding the safety of VIOXX and its results.

54. Defendant Celia Colbert ("Colbert") was, at all relevant times, an assistant general counsel for Merck, which reasonably would have made her privy to information regarding the safety of VIOXX and its results.

55. Defendant Linda M. Distlerath ("Distlerath") was Vice President of Global Health Policy and Vice President of Public Affairs during the Class Period, which reasonably would have made her privy to information regarding the safety of VIOXX and its results.

56. Defendant Caroline Dorsa ("Dorsa") has been Vice President and Treasurer of Merck since September 1999, which reasonably would have made her privy to information regarding the safety of VIOXX and its sales.

57. Defendant Bernard J. Kelley ("B. Kelley") was a senior executive in charge of manufacturing of drugs, which reasonably would have made him privy to information regarding the safety of VIOXX and its risks.

58. Defendant Per G.H. Lofberg ("Lofberg") was President of Merck-Medco Managed Care, L.L.C. ("MMMC"), a wholly-owned subsidiary of Merck until January 2000, when he became Chairman of MMMC, which reasonably would have made him privy to information regarding the safety of VIOXX and its sales.

59. Defendant Per Wold-Olsen ("Wold-Olsen") was, throughout the Class Period, President of Human Health Europe, Middle East & Africa and was responsible for the Company's prescription drug business in Europe, the Middle East and Africa, which

reasonably would have made him privy to information regarding the safety of VIOXX and its sales.

59(a). Defendant Lloyd C. Elam ("Elam") was a director of Merck from the beginning of the Class Period through at least March 2001, which reasonably would have made him privy to information regarding the safety of VIOXX and its sales.

60. Defendants Gilmartin, Scolnick, Frazier, Henriques, Lewent, Anstice, Cole, Clark, Colbert, Distlerath, Dorsa, B. Kelley, W. Kelley, Lofberg, Wold-Olsen, and Elam are collectively referred to herein as the "Insider Trading Defendants."

61. The following defendants, previously named as "ABC Insurance Corporation," were, during the Class Period, Merck's directors' and officers' liability insurers, and each issued directors, officer and/or corporate securities liability policies that provide coverage for claims made herein for one or more of the defendants to this action, and each of the following defendant insurance carriers were timely put on notice of some or all of the claims set forth in this Complaint:

(a) ACE American Insurance Company;

(b) ACE Bermuda Insurance Ltd.;

(c) Allied World Assurance Company, Ltd.;

(d) American Alternative Insurance Corporation;

(e) American Casualty Company of Reading, Pennsylvania;

(f) Arch Reinsurance Ltd.;

(g) AXIS Reinsurance Company;

(h) Axis Specialty Limited;

(i) Federal Insurance Company;

(j) Gerling-Konzern Allegemeine Versicherungs A.G.;

(k) Houston Casualty Company;

(l) Max Re Ltd.;

(m)North Rock Insurance Company Limited;

(n) SR International Business Insurance Company Ltd.;

(o) Steadfast Insurance Company;

(p) The St. Paul Mercury Insurance Company;

(q) Twin City Fire Insurance Company;

(r) XL Insurance (Bermuda) Ltd.;

(s) XL Insurance Switzerland (as successor to Winterthur Swiss Insurance Company); and

(t) Zurich American Insurance Company.

Collectively, the above defendants shall be referred to as the "Insurer Defendants." The Insurer Defendants are liable jointly and *in solido* with their insureds under La. R.S. 22:655, the "Direct Action" statute.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

62. Plaintiffs bring this action as a class action, pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of a Class consisting of all persons and entities who purchased the securities of Merck during the period from May 21, 1999 through October 29, 2004, inclusive. Excluded from the Class are all defendants; the affiliates and subsidiaries of the Company; the officers and directors of the Company and

its subsidiaries and affiliates at all relevant times; members of the immediate family of any excluded person; the legal representatives, heirs, successors, and assigns of any excluded person or entity; and any entity in which any excluded person or entity has or had a controlling interest.

63. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Merck had billions of shares of common stock outstanding, which were actively traded on the NYSE. The average daily trading volume during the Class Period was more than 6.5 million shares. While the exact number of Class members is unknown to Plaintiffs at this time, Plaintiffs believe that there are at least thousands of members of the proposed Class. Members of the Class can be identified from records maintained by Merck or its transfer agent and can be notified of the pendency of this action by mail and publication using forms of notice similar to those customarily used in securities class actions.

64. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class were similarly damaged by Defendants' wrongful conduct as complained of herein.

65. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests that conflict with the interests of the Class.

66. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the

Class. Among the questions of law and fact common to the Class are:

(a) whether Defendants' statements and omissions during the Class Period materially misrepresented the safety and commercial viability of VIOXX;

(b) whether Defendants' acts and omissions as alleged herein violated the federal securities laws;

(c) whether the Individual Defendants are personally liable for the alleged misrepresentations or omissions described herein;

(d) whether Defendants' misrepresentations and omissions caused the price of Merck securities to be purchased by Class members at artificially inflated prices and whether Class members suffered a compensable loss caused by Defendants' alleged misconduct; and

(e) whether the members of the Class have sustained damages and the proper measure of damages.

67. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. As the damages suffered by many individual Class members may be small relative to the expense and burden of individual litigation, it is practically impossible for most members of the Class to redress individually the wrongs done to them. There will be no difficulty in the management of this action as a class action.

SUBSTANTIVE ALLEGATIONS

Traditional NSAIDs

68. Musculosketal problems producing pain and inflammation are common. Until 1998, NSAIDs, such as aspirin, ibuprofen, and naproxen, were the most common medications for treating musculoskeletal problems. NSAIDs reduce inflammation and pain, and are widely used to treat persons suffering from arthritis and muscle pain.

69. GI side effects limit the use of NSAIDs. More than 100,000 patients are hospitalized and 16,500 die each year in the United States as a result of NSAID-associated GI events.

70. Most NSAIDs inhibit two enzymes — cyclooxygenase-1 ("COX-1") and cyclooxygenase-2 ("COX-2") — that are involved in the synthesis of important chemical compounds that control a wide variety of physiological functions throughout the body. Those compounds are known as prostaglandins or prostanoids.

71. COX-1 is associated with the maintenance of GI mucous and platelet aggregation. COX-2 is associated with response to pain and inflammation.

72. Traditional NSAIDs, such as aspirin, ibuprofen, and naproxen, operate non-selectively. That is, traditional NSAIDs inhibit both COX-1 and COX-2 at the same time. The beneficial effects of traditional NSAIDs (*i.e.*, the reduction of inflammation and pain) are related to the inhibition of COX-2. The harmful GI side effects are related to the suppression of COX-1.

Defendants Develop VIOXX

73. VIOXX is the brand name of rofecoxib, a member of the NSAID class of anti-inflammatory drugs. Unlike aspirin, ibuprofen, and naproxen, VIOXX is a "selective" NSAID, which was designed to suppress COX-2 without materially affecting COX-1. The intent was to maintain all of the beneficial effects of traditional NSAIDs (the reduction of inflammation and pain) while avoiding the risk of serious GI side effects.

74. Significantly, Merck did not represent that VIOXX was any more effective than traditional NSAIDs like ibuprofen and naproxen at treating inflammation and pain. The sole advantage of VIOXX over other NSAIDs was its purported improved safety profile.

Merck's Financial Prospects Depended Upon The Success Of VIOXX

75. Even prior to the commercial introduction of VIOXX to the market on May 21, 1999, Defendants knew that the success of VIOXX was crucial to Merck's future financial performance and success. Merck's 1998 Annual Report quoted Dr. Beth Seidenberg, Vice President, Clinical Research: "***Everybody involved [in the VIOXX project] knew how extraordinarily important Vioxx is to patients with osteoarthritis and to Merck***" (emphasis added).

76. As illustrated by the chart below, the patents for nine major drugs, accounting for more than 70% of the Company's pharmaceutical sales in 1999, and more than 65% of total pharmaceutical sales in 2000, were set to expire by 2007. This vanishing pipeline of pharmaceutical revenue created an immense amount of

pressure on Defendants to ensure that VIOXX was the Company's next multi-billion dollar blockbuster drug.

(All Figures in Millions Except %)	Patent Expiration	2000				1999			
		Sales	% Rx Sales	% Total Sales	Rx Sales Rank	Sales	% Rx Sales	% Total Sales	Rx Sales Rank
Zocor	2006	5280	25.63	13.08	1	4495	25.72	13.74	1
Vasotec	2000	1790	8.69	4.43	3	2305	13.19	7.05	2
Prilosec*	2001	1355	6.58	3.36	5	1250	7.15	3.82	4
Fosamax	2007	1275	6.19	3.16	6	1045	5.98	3.19	5
Prinivil	2001	1075	5.22	2.66	7	815	4.66	2.49	7
Singulair	2003	860	4.17	2.13	8	500	2.86	1.53	11
Pepcid	2000	850	4.13	2.11	9	910	5.21	2.78	6
Mevacor	2001	520	2.52	1.29	12	600	3.43	1.83	9
Proscar	2006	470	2.28	1.16	13	450	2.57	1.38	13
Totals		13475	65.41	33.38		12370	70.77	37.81	

** Merck's SEC filings indicate that it receives supply payments on U.S. sales of Prilosec under an agreement with AstraZeneca (AZN)*

77. Merck was encountering serious difficulties in the development of its new drug for depression, MK-869, thus jeopardizing the Company's pipeline of future, new drug revenues and intensifying the pressure on Defendants to ensure VIOXX was a success. On January 22, 1999, Merck announced it would ***not*** begin Phase III trials for MK-869. On January 25, 1999, analyst James P. Keeney of ABN Amro noted that the ***"setback imposes a severe burden on [Merck's] remaining major R&D hope, the VIOXX COX-2 drug, which now must be a spectacular-selling oral antiarthritic for the company to at least show double-digit EPS growth in the post-1999 period"*** (emphasis added).

78. Adding to the pressure on Defendants that VIOXX be a success, Pfizer and Monsanto were already ahead of Merck in jointly developing Celebrex, another COX-2 inhibitor. On December 31, 1998, the FDA approved the New Drug Application ("NDA") for Celebrex. Immediately thereafter, and almost five months before the FDA approved the NDA for VIOXX, Pfizer and Monsanto staged an extremely aggressive launch of Celebrex, including offering patients free trials.

79. According to a January 28, 1999 Prudential analyst report, which was based, at least in part, on information and guidance provided by Defendants, in response to the aggressive launch of Celebrex, Merck expected to add 700 salespeople in the first half of 1999 to support the introduction of VIOXX and would counter with a major marketing campaign of its own.

80. On April 14, 1999, *The Wall Street Journal* reported: "VIOXX is already a step behind the competition in the huge, lucrative arthritis-relief market." *The Wall Street Journal* article noted that Celebrex already had become "one of the most successful new drugs in industry history."

81. On May 21, 1999, the day Defendants introduced VIOXX to the market (and the first day of the Class Period), a *Dow Jones Newswire* report elaborated on the importance of VIOXX to Merck, and the anticipated competition between VIOXX and Celebrex: "The battle for this summer's blockbuster may not occur in movie theaters, but instead in the corner drugstore." The report quoted David Saks, a pharmaceutical analyst at Gruntal & Co.: "***VIOXX to Merck is like the hot movie 'Star Wars' to the movie industry. . . . It's the biggest product for Merck***"

(emphasis added). That day, Merck common stock closed at $69.20 — $2.47 higher than the previous day's closing price — on heavy trading volume of 7,578,900, which was 53% greater than the previous day's trading volume.

82. On January 10, 2001, *The Wall Street Journal*, in an article entitled "When Its Patent Expired Merck Didn't Merge — It Found New Drugs," reported how the Company's fortunes were inextricably tied to the success of VIOXX: "***Merck's success demonstrates that in the drug business, as in Hollywood, one big hit can sway the fate of an entire company***" (emphasis added). The article quoted defendant Scolnick, speaking about the two original compounds Merck had tested in developing VIOXX:

> "If those first two compounds had failed [in human trials] and we had by chance to rely on the fifth or sixth one" years later, he says "***we would be a very different company***" (emphasis added).

83. During the Class Period, Merck was also experiencing problems with ARCOXIA, the Company's planned successor to VIOXX. This further increased Merck's dependence on VIOXX, and further motivated Defendants to conceal VIOXX's serious adverse cardiovascular profile from the market, *i.e.*, Merck could continue to reap significant profits from its "blockbuster" drug VIOXX as long as the truth concerning its cardiovascular risks was concealed from the market.

84. A November 14, 2004 *New York Times* article, entitled "Despite Warnings, Drug Giant Took Long Path to Vioxx Recall," quoted drug industry analyst Michael

Krensavage at Raymond James & Associates: "***Vioxx was Merck's savior, it's as simple as that***" (emphasis added).

85. Indeed, for the years VIOXX was marketed, as a result of Defendants' wrongful conduct, as detailed herein, VIOXX was Merck's second best selling drug:

- In 2000, sales of VIOXX were more than $2.1 billion, approximately 10.7% of Merck's pharmaceutical sales, and more than 5.3% of the Company's total sales.

- In 2001, sales of VIOXX were more than $2.3 billion, more than 11% of Merck's pharmaceutical sales, and more than 4.9% of the Company's total sales.

- In 2002, sales of VIOXX were more than $2.5 billion, approximately 11.7% of Merck's pharmaceutical sales, and almost 4.9% of the Company's total sales.

- In 2003, sales of VIOXX were more than $2.5 billion, approximately 12.5% of Merck's pharmaceutical sales, and more than 11.4% of the Company's total sales.

- During the first six months of 2004, the year VIOXX was withdrawn, sales of VIOXX were more than $1.3 billion.

Accordingly, by 2000, Merck was reaping more than $175 million in sales every month VIOXX remained on the market — a number that increased during the Class Period.

Even Prior To Introducing VIOXX To The Market Defendants Knew Of VIOXX's Adverse Safety Profile

86. Notwithstanding defendant Gilmartin's representation on September 30, 2004, the day Merck withdrew VIOXX from the market, that the report of cardiovascular problems associated with VIOXX was "unexpected," according to *The Wall Street Journal* article (November 1, 2004), Defendants knew, at least ***as early as 1996***, of the serious safety issues with VIOXX, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

87. The November 1, 2004, *Wall Street Journal* article reported, based on among other things, internal Merck documents, that Defendants had known about VIOXX's adverse safety profile, and had acted to suppress the truth since as early as 1996:

> When Merck & Co. pulled its big-selling painkiller Vioxx off the market in September, Chief Executive Raymond Gilmartin said the company was "really putting patient safety first." He said the study findings prompting the withdrawal, which tied Vioxx to heart-attack and stroke risk, were "unexpected." But internal Merck e-mails and marketing materials as well as interviews with outside scientists show that the company fought forcefully for years to keep safety concerns from destroying the drug's commercial prospects.
>
> Merck's first worry, in the mid-to-late 1990s, was that its drug would show

> greater heart risk than cheaper painkillers that were harsh on the stomach but were believed to reduce the risk of heart attacks. Several company officials discussed in e-mails how to design a study that would minimize the unflattering comparison, even while admitting to themselves that it would be difficult to conceal.

88. *The Wall Street Journal* article described in detail a number of internal Company e-mails and other documents that evidence Defendants' awareness of the seriousness of the safety issues affecting VIOXX well before the beginning of the Class Period. According to *The Wall Street Journal*:

> A November 21, 1996 memo by a Merck official shows the company wrestling with this issue. They wanted to conduct a trial to prove Vioxx was gentler on the stomach than older painkillers. But to show the difference most clearly, the Vioxx patients couldn't take any aspirin. In such a trial, "there is a substantial chance that significantly higher rates" of cardiovascular problems would be seen in the Vioxx group, the memo said. A similar view was expressed in a February 25, 1997 e-mail by a Merck official, Briggs Morrison. He argued that unless patients in the Vioxx group also got aspirin, "***you will get more thrombotic events***" — that is, blood clots — "***and kill [the] drug.***" In response, [defendant] Reicin, now a Merck vice president for clinical research, said in

> an e-mail that the Company was in a "no-win situation." Giving study subjects both Vioxx and aspirin, she wrote, could increase the "relative risk," apparently referring to gastrointestinal problems. But, she added, ***"The possibility of increased CV [cardiovascular] events is of great concern."*** From the context, it seems Dr. Reicin meant "increased" relative to older drugs. She added in parentheses: "I just can't wait to be the one to present those results to senior management!" She proposed that people with high risk of cardiovascular problems be kept out of the study so the difference in the rate of cardiovascular problems between the Vioxx patients and the others "would not be evident" (emphasis added).

Extensive Pre-Class Period Testing Revealed to Defendants VIOXX's Serious Cardiovascular Risks

89. Prior to VIOXX being approved by the FDA, Defendants conducted extensive studies and analyses of VIOXX, including clinical studies involving humans. According to Merck's November 23, 1998 press release, which was issued more than six months prior to VIOXX being approved by the FDA: ***"[T]he [VIOXX NDA] application included results from 68 studies and nearly 10,000 patients that evaluated VIOXX"*** (emphasis added).

90. According to Dr. Eric Topol, Chief of Cardiovascular Medicine at the Cleveland Clinic, a never-published 1998 internal Merck clinical trial

entitled Study 090 revealed that, of 978 patients studied, serious cardiovascular events — including ***heart attack and stroke — occurred six times more frequently in patients given VIOXX than in patients given a different arthritis drug or placebo.*** (Dr. Topol presented this information, after the Class Period, on the November 14, 2004 edition of CBS's *60 Minutes*.) Merck never disclosed either the adverse findings of Study 090 or that those findings were independently replicated by a Merck-sponsored study announced in early 2000 called the VIOXX Gastrointestinal Outcomes Research Study (the "VIGOR Study"). The VIGOR Study included approximately 8,100 rheumatoid arthritis patients and was intended to demonstrate that VIOXX reduced the risk of serious GI side affects associated with the use of other NSAIDs.

91. In addition, *The New York Times*, in an article entitled "Evidence in VIOXX Suits Shows Intervention by Merck Officials," which was published after the Class Period (April 24, 2005), reported that even before the drug's introduction to the market, Defendants established a committee to review the numerous reports of cardiovascular events associated with VIOXX:

> In 1998, Merck had created a committee of academic researchers to review the case reports for many patients who had suffered suspected heart problems in clinical trials of Vioxx and Arcoxia, a Merck arthritis drug that has still not been approved.

As detailed herein, *The New York Times* article also reported how Defendants had distorted the results of a

Class Period clinical study to hide the cardiovascular risks associated with VIOXX.

92. Notwithstanding Defendants' knowledge, even before the beginning of the Class Period, of the serious cardiovascular risks posed by VIOXX, which jeopardized the drug's commercial viability, and the Company's financial prospects, Defendants falsely conditioned the market to believe VIOXX was safe, would be a commercial success, and would assure Merck a significant revenues stream from the drug throughout the life of Merck's patent. Such materially false and misleading statements continued to affect the trading price of Merck securities during the Class Period.

93. For example, on December 9, 1998, at Merck's annual analyst meeting, defendant Scolnick boasted: "Short-term high dose, long-term low dose, it's a wonderful drug . . . VIOXX has lived up to our highest expectations." Defendant Scolnick asserted his belief that VIOXX would get fast track approval from the FDA. According to Scolnick, in one major trial, VIOXX's safety profile showed ***"statistical equivalence"*** to placebo (emphasis added). Defendant Scolnick further represented that Merck has ***"extensive data"*** (emphasis added) documenting VIOXX's effectiveness in treating pain in different populations.

Defendants' Wrongful Conduct During The Class Period

94. On May 21, 1999, the first day of the Class Period, Defendants issued a Company press release announcing that VIOXX "has received marketing approval from the U.S. Food and Drug Administration. VIOXX has been approved for the relief of osteoarthritis

(OA), management of acute pain in adults, and treatment of menstrual pain (primary dysmenorrheal)." With respect to the drug's side effects, the press release noted: "The most common side effects reported in clinical trials with VIOXX were upper respiratory infection, diarrhea and nausea."

95. The May 21, 1999 press release was materially false and misleading in that, among other things, once Defendants chose to speak about the "side effects" of VIOXX, they had a duty to speak fully and truthfully, and to disclose the most significant side effects of the drug, namely the serious cardiovascular risks, which jeopardized VIOXX's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

96. Defendants' misstatements concerning VIOXX's adverse safety profile, which jeopardized the commercial viability of the drug and its ability to generate substantial revenues over the life of Merck's patent, were not limited to the SEC filings, press releases, and conference calls with securities analysts detailed herein. Defendants also made misstatements in VIOXX's labeling leaflet, which is the multi-page, small print pamphlet inserted in the box in which a pharmaceutical product is sold (but not the "sticker" that is attached to the container of the product itself). For instance, during the Class Period, Defendants issued four different versions of the label leaflet for VIOXX which was included with every package, all of which misrepresented and omitted material facts concerning the cardiovascular risks attributable to VIOXX. Such labeling leaflet information with respect to a major product is regularly considered by analysts and other

financial market participants in assessing a company's business, products, and prospects.

97. FDA regulations require a drug label leaflet to "contain a summary of the essential scientific information needed for the safe and effective use of the drug." 21 C.F.R. § 201.56(a)(2004). The label leaflet must be "informative and accurate and neither promotional in tone nor false or misleading in any particular." *Id.* at § 201.56(b). The regulations also require that information concerning risks associated with the drug be set forth in the following form:

> ***Contraindications: Under this section heading, the labeling shall describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit.*** These situations include administration of the drug to patients known to have a hypersensitivity to it; use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it; or continued use of the drug in the face of an unacceptably hazardous adverse reaction. Known hazards and not theoretical possibilities shall be listed . . . . (21 C.F.R. § 201.57(d) (v)(d)(j)) (emphasis added); and
>
> ***Warnings***: Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and

> steps that should be taken if they occur. ***The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved*** . . . . 21 C.F.R. § 201.57(3) (v)(e) (emphasis added).

98. Securities analysts who specialize in pharmaceutical companies are well aware of these requirements, and study product label leaflets as part of their analysis of a drug's commercial viability, long-term growth and revenue prospects, and potential for product liability exposure. Thus, truthful labeling pursuant to FDA regulations is an essential component of the market's valuation of the performance and prospects of a pharmaceutical company, including but not limited to discounted cash flow, as well as the company's securities.

99. As detailed below, Defendants recognized that including information about the cardiovascular risks in the VIOXX label leaflet — particularly in the "Contraindications" and "Warnings" sections — would adversely impact sales of VIOXX, especially because the Celebrex label leaflet only included general boilerplate language concerning possible cardiovascular risks, which was set forth at the very end of the label leaflet, after the "Contraindications" and "Warnings" sections. Thus, it was no coincidence that none of the four different VIOXX label leaflets that were used when VIOXX was on the market contained any, yet alone truthful, language that adequately or properly disclosed VIOXX's cardiovascular risks in the "Contraindications" or "Warnings" sections. Accordingly, all of the VIOXX

labels wrongfully minimized VIOXX's serious cardiovascular risks.

100. The initial VIOXX label leaflet (the "First VIOXX Label"), which was in use from May 21, 1999 through April 11, 2002, included the following materially misleading and general boilerplate language concerning "spontaneous events [that] occurred" in an Osteoarthritis Study:

> In the OA Studies, the following spontaneous events occurred in >0.1 to 1.9% of patients treated with VIOXX ***regardless of causality*** (emphasis added).

101. This general boilerplate language also listed ten different body systems, including, among others "Body as Whole," "Eyes, Ears, Nose, and Throat," as well as "Cardiovascular System," which were then further broken down into more than 100 types of events, including "cough," "dry mouth," and "insect bite reaction." Thus, the First VIOXX Label not only buried the threat of serious cardiovascular risks to VIOXX users, but was intended to, and did, lead the public to believe whatever adverse cardiovascular events had been experienced by users of VIOXX were statistically irrelevant and mere coincidence. Similarly, the second section contained the following general boilerplate language: "Other serious adverse reactions which occur rarely (<0.1%), *regardless of causality*," which was followed by a list of four body systems, including Urogenital, and approximately 20 type events, including colitis and urolithiasis.

102. Accordingly, Defendants' statements in this VIOXX label were materially false and misleading because, among other things, they failed to disclose that

there was a direct causal relationship between VIOXX and cardiovascular events *i.e.*, that the use of VIOXX significantly increased the risk of having a heart attack or other serious cardiovascular event, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

103. Shortly after Defendants introduced VIOXX to the market in May 1999, Defendants were informed by Merck's own sales representatives that VIOXX was responsible for causing cardiovascular events. For example, in the summer of 1999, FME-1 was informed by one of Merck's customers, a neurologist, that two of his patients had died as a result of using VIOXX. ***That information was reported to Merck.***

104. On July 23, 1999, Defendants issued a Company press release announcing financial results for the second quarter 1999, the period ending June 30, 1999. Defendant Gilmartin commented on the Company's performance:

> Sales growth for the quarter and the first half of 1999 was led by the established major products, the newer products including the 1999 launch of Vioxx, as well as growth from the Merck-Medco Managed Care business . . . . Solid volume gains in both our domestic and international operations as well as a 3 point benefit attributable to the restructuring of Astra Merck, Inc. (AMI) contributed to the second quarter results.

105. In the press release, Defendants also elaborated on the purported success of VIOXX, as well

as additional clinical studies being conducted on the drug:

> Following a six-month priority review on May 20 the FDA cleared VIOXX, Merck's once-daily COX-2 specific inhibitor, for relief of the signs and symptoms of osteoarthritis, management of acute pain in adults, and treatment of menstrual pain. Since then, more than 400,000 U.S. patients have taken the Product. Merck has introduced VIOXX in nine other countries including the United Kingdom, Switzerland and Mexico.
>
> The Company is conducting additional clinical studies with VIOXX to determine whether it is useful in treating rheumatoid arthritis and in preventing and treating Alzheimer's disease. Studies will begin later this year to ascertain whether VIOXX might help to prevent colon cancer.

106. The July 23, 1999 press release was materially false and misleading because, among other things, once Defendants chose to speak about the purported success of VIOXX, they had a duty to speak fully and truthfully, and to disclose the serious cardiovascular risks attributable to the drug, which jeopardized VIOXX's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

107. On August 12, 1999, Defendants filed with the SEC Merck's Form 10-Q for the second quarter 1999. The Form 10-Q was signed by defendant Henriques, and repeated the same materially false and

misleading statements concerning the purported success of VIOXX that were made in the July 23, 1999 press release referred to above.

108. On October 19, 1999, Defendants issued a Company press release announcing the findings of a paper by Dr. Morrison of Merck Research Laboratories, that "VIOXX relieved menstrual pain as effectively as the most commonly used prescription treatment for that condition, naproxen sodium (3), and better than placebo." Defendants further emphasized the purported success of VIOXX: "[S]ince its approval by the FDA in May, more than 2.2 million prescriptions have been written for VIOXX in the United States, making it one of the most successful product introductions in the pharmaceutical industry's history."

109. Although Defendants chose to make much of Dr. Morrison's purported findings concerning the effectiveness of VIOXX in treating menstrual pain, they chose not to disclose his earlier warnings concerning the thrombotic events associated with VIOXX, which he had communicated to Defendants in 1997, but which were not revealed publicly until November 1, 2004 by *The Wall Street Journal*. The October 19, 1999 press release was materially false and misleading because, among other things, once Defendants chose to speak about the purported success and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent, and which, as evidenced by, among other things, Dr. Morrison's 1997 warning referred to above, were clearly known to Defendants, even before the commercial introduction of VIOXX.

110. On October 21, 1999, Defendants issued a Company press release announcing Merck's financial results for the third quarter 1999, the period ending September 30, 1999. Commenting on the Company's performance, in that press release, defendant Gilmartin stated:

> ***Sales growth for the quarter and nine months of 1999 was led by*** the established major products, ***the newer products, including VIOXX***, and growth from the Merck-Medco Managed Care business .... Solid volume gains in both our domestic and international operations contributed to the third quarter results (emphasis added).

111. In the press release, Defendants also stated:

> In just 20 weeks on the market in the United States, VIOXX has become the country's fastest growing prescription arthritis medicine. U.S. physicians have written more than 2 million prescriptions for Merck's newest medicine, which is used to relieve the signs and symptoms of osteoarthritis, manage acute pain in adults and treat menstrual pain.
>
> Merck has introduced VIOXX in 22 other countries, including the United Kingdom, Switzerland and Mexico. The Company is conducting extensive clinical studies with VIOXX to evaluate its efficacy in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease. Studies will begin

later this year to ascertain whether VIOXX might help prevent colon cancer.

112. The October 21, 1999 press release was materially false and misleading because, among other things, once Defendants chose to speak about the purported success of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning VIOXX's serious cardiovascular risks, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

113. Four days later, on October 25, 1999, Defendants issued a Company press release announcing the results of a new study that showed that osteoarthritis patients taking VIOXX "developed significantly fewer endoscopic ulcers than patients taking ibuprofen, a commonly used arthritis medicine." Defendants also stated, as they had previously, that "[i]n other studies, the most common side effects reported in clinical trials with VIOXX were upper respiratory infection, diarrhea, nausea and high blood pressure."

114. The October 25, 1999 press release was materially false and misleading because, among other things, once Defendants chose to speak about the side effects of VIOXX, they had a duty to speak fully and truthfully and to disclose the most significant side effects of the drug, namely the serious cardiovascular risks, which jeopardized VIOXX's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

115. On or about November 1, 1999, Defendants publicly issued two promotional pieces, entitled "TEN REASONS WHY VIOXX IS BETTER THAN

CELEBREX," and "VIOXX vs. Celebrex Poem," each of which stated, in part:

> "VIOXX HAS ENDOSCOPY STUDIES SHOWING A SAFER THAN PLACEBO INCIDENCE RATE OF GASTRODUODENAL ULCERS;"
>
> "Your patients in pain – they give you their grief; A Cox-II is the answer for their pain relief;"
>
> "VIOXX of course – the answer again, It's stronger, lasts longer, is faster, and then its safer. . . ."

116. The promotional pieces referred to in the previous paragraph were each materially false and misleading because, as the FDA admonished Merck in a Warning Letter referred to below (the "First Warning Letter"), they misrepresented VIOXX's safety profile, and made "unsubstantiated comparative claims" that were "lacking in fair balance." In addition, once Defendants chose to speak about the purported success and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

117. On or about November 12, 1999, Defendants filed with the SEC Merck's Form 10-Q for the third quarter 1999. The Form 10-Q was signed by defendant Henriques, and repeated the same materially false and misleading statements concerning the purported success of VIOXX that were made in the Company's October 21, 1999 press release referred to above.

118. On November 23, 1999, Defendants issued a Company press release announcing the results of a study published in the *Journal of the American Medical Association* ("*JAMA*"), which found that VIOXX "significantly reduced the risk of gastrointestinal (GI) side effects" compared to other commonly prescribed non-steroid anti-inflammatory drugs. Defendants also stated that "[c]ommon side effects reported in clinical trials with VIOXX were upper-respiratory infection, diarrhea, nausea and high blood pressure."

119. The November 23, 1999 press release was materially false and misleading because, among other things, once Defendants chose to speak about the purported success and advantages of VIOXX and about its side effects, they had a duty to speak fully and truthfully and to disclose the most significant side effects of the drug, namely the serious cardiovascular risks, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

120. On December 16, 1999, the FDA sent the First Warning Letter to Merck. Pursuant to FDA policy and practice, Warning Letters are sent only to address serious circumstances. Although the First Warning Letter solely concerned Defendants' "violation of the Federal Food, Drug and Cosmetic Act (Act) and its regulations" with respect to promotional pieces touting VIOXX's purported beneficial GI benefits, the First Warning Letter was indicative of Defendants' willingness and common course of conduct throughout the Class Period of failing to disclose significant risks attributable to VIOXX, and to misrepresent its safety and superiority to competing products.

121. The FDA, in the First Warning Letter, which was addressed to Ellen R. Westrick, Executive Director, Office of Medical/Legal, admonished Defendants that the marketing materials being used to promote VIOXX were deceptive. Among other things, the First Warning Letter stated that the ***"promotional pieces... that promoted VIOXX... are false or misleading because they contain misrepresentations of VIOXX's safety profile, unsubstantiated comparative claims, and are lacking in fair balance"*** (emphasis added).

122. The First Warning Letter commented, with respect to "misrepresentations of VIOXX's safety profile," that:

> You present claims that misrepresent the safety profile for Vioxx, including but not limited to, "VIOXX HAS ENDOSCOPY STUDIES SHOWING A SAFER THAN PLACEBO INCIDENCE RATE OF GASTRODUODENAL ULCERS." [Emphasis in the original.] However, ***this claim is in direct contrast with the approved product labeling (PI)*** that states, ". . . the studies cannot rule out at least some increase in the rate of endoscopic gastrodudenal ulcers when comparing Vioxx to placebo." Furthermore, this claim suggests that Vioxx is safer than placebo in regards to clinically significant gastrodudenal events. However, the PI states, "The correlation between findings of endoscopic studies, and the relative incidence of clinically serious upper GI events that may be

> observed with different products, has not been fully established." Moreover, this claim minimizes the warning in the PI that states, "Serious gastrointestinal toxicity such as bleeding, ulceration, and perforation of the stomach, small intestine or large intestine, can occur at any time, with or without warning symptoms . . .," and omits material fact in the PI which states, "Serious clinically significant upper GI bleeding has been observed in patients receiving VIOXX in controlled trials . . ." Therefore, we object to this claim because it minimizes the GI warning associated with Vioxx and is inconsistent with the data in the PI (emphasis added).

123. The FDA's First Warning Letter cited Merck's minimization of VIOXX's risks as deceptive:

> Although these pieces contain numerous claims for the efficacy and safety of VIOXX, ***you have not presented any risk information concerning the contraindications, warnings, precautions, or adverse events associated with VIOXX's use. Therefore, we consider these promotional pieces to be lacking in fair balance***. Furthermore, these promotional pieces are in violation of the Act because the approved product labeling for VIOXX did not accompany them (emphasis added).

124. The FDA's First Warning Letter also chastised Merck for making unfounded claims that VIOXX was better than Celebrex:

> ***You also present several unsubstantiated comparative claims to Celebrex*** (celecoxib), including but not limited to, "VIOXX of course - the answer again, It's stronger, lasts longer, is faster, and then it's safer . . . ." [The FDA found that] this claim suggests VIOXX is more efficacious and has a superior safety profile compared to Celebrex, when such has not been demonstrated by substantial evidence. Therefore, this unsubstantiated comparative claim is misleading (emphasis added).

125. Notably, the First Warning Letter made no reference to the cardiovascular risks associated with VIOXX, or Defendants' failure to disclose those risks. Rather, Defendants had successfully concealed, distorted, and obscured the truth about VIOXX's significant cardiovascular risks not only from the public, patients, and the medical community, but from the FDA as well.

126. On January 26, 2000, Defendants issued a Company press release announcing Merck's financial results for the fourth quarter and full year 1999, the periods ending December 31, 1999. The press release quoted defendant Gilmartin as follows:

> Sales growth for the quarter and the year was led by the established major products, the newer products, including VIOXX, as

> well as growth from the Merck-Medco Managed Care business.
>
> ***VIOXX is the fastest growing prescription arthritis and pain medicine in the United States and represents one of the most successful product introductions in the pharmaceutical industry's history*** (emphasis added).

127. The January 26, 2000 press release also stated:

> Since its introduction almost eight months ago in the United States, more than 5 million prescriptions have been written for VIOXX. With its exceptional product profile VIOXX is the country's fastest growing prescription arthritis medicine.

128. The January 26, 2000 press release was materially false and misleading in that, among other things, once Defendants chose to speak about the purported success and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose the serious cardiovascular risks attributed to VIOXX, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

129. By early March 2000, Defendants were aware of the results of the VIGOR Study, which Merck commenced in January 1999, prior to the Class Period, and even prior to the FDA's approval of VIOXX, to investigate the purported GI benefits of VIOXX as compared to traditional NSAIDs.

130. Participants in the VIGOR Study received a daily dose of VIOXX (50mg) or naproxen (1000mg).

131. In designing the VIGOR Study, Merck took the exceptional step of including an "external ***Vascular Event Committee*** (VEC), containing three separate subspecialty committees (***cardiac***, cerebrovascular, and peripheral), [] for surveillance, monitoring, and adjudication of vascular events occurring in COX-2 inhibitor trials" (emphasis added). As one prestigious medical journal, *The Lancet*, later concluded with respect to Merck including a VEC as part of the VIGOR Study, Merck ***"apparently was aware of possible myocardial toxicity before the [VIGOR] trial, because it set in place a separate adjudication procedure to study the event"*** (emphasis added).

132. Internal Company documents evidence that Defendants, recognizing the importance of the VIGOR Study to the continued success of VIOXX and its consequent importance to Merck's performance and prospects, engaged in a systematic effort to influence the Study's results. For example, on February 11, 2000, prior to the VIGOR Study's final results (being announced to the public), defendant Scolnick sent an email to Deborah Shapiro, whom defendant Scolnick believed was the "unblinded statistician" for the VIGOR Study. Defendant Scolnick's email attached a copy of a just-issued Salomon Smith Barney analyst report which stated, among other things, that although "Vioxx stunned [Monsanto] (and marketing partner Pfizer) during the 2H99 . . . [i]n 2000 we expect the momentum to shift back to MTC/PFE," *i.e.*, to Celebrex.

133. In his February 11, 2000 email to Deborah Shapiro, defendant Scolnick, in response to the Salomon

Smith Barney analyst report, made the following request:

> Deborah. Please read this story. It is my understanding that you are the unblinded statistician in our Vigor study. In the last few days we are being pounded by stories like this. As with the key aggrastar when Snappin and i [sic] had to make a decision as soon as you know what the answer is I would like a confidential meeting with you. ***The situation cannot simply follow the "book" ways of knowing.*** Please let me know when I can talk to you confidentially. You can reach me when this time comes at work at home PRIVACY – by voice mail (private) or anywhere by email-I am the only one who listens to my voice mail or email. Thanks I hope your lucky rabbit's foot is as good as it was with mevacor afcaps/Ed Scolnick (emphasis added).

134. Commenting on the VIGOR Study results, the FDA concluded: "[e]valuation of safety by routine parameters showed no advantage of [VIOXX] rofecoxib over naproxen." In fact, far from demonstrating an improved safety profile for VIOXX, as compared to naproxen, the VIGOR Study also evidenced that:

(a) Patients on VIOXX were five times more likely to suffer a heart attack as compared to patients on naproxen;

(b) Patients on VIOXX were 2.3 times more likely to suffer serious cardiovascular disease (including heart attacks, ischemic stroke, unstable angina, and sudden

unexplained death) as compared to patients on naproxen; and

(c) Patients on VIOXX actually suffered more cases of serious disease (either gastrointestinal or cardiovascular) than did naproxen users (61 and 57 cases respectively).

135. According to a *New York Times* article, entitled "Despite Warnings, Drug Giant Took Long Path to VIOXX Recall," which was published after the Class Period (November 14, 2004), notwithstanding Defendants' representations to the market during the Class Period, Defendants were very aware of the devastating significance of the VIGOR Study results to VIOXX and the Company's financial dependence on the drug:

> Company executives and researchers say that from the moment they were told in March 2000 about the preliminary results from the Vigor trial, they sought every possible explanation for the signs of increased cardiovascular risk. ***And, they say, they were open to the possibility that VIOXX was at fault.***
>
> "We were stunned," by the findings, said [defendant] Dr. Alise S. Reicin, the Merck researcher who ran the VIGOR study. ***"It's fair to say that we were all concerned"*** (emphasis added).

136. Defendants' internal concerns about the VIGOR Study results, evidencing VIOXX's adverse cardiovascular profile, and Defendants' desire to find an explanation to provide to the public for its results, were

understandable. Not only did the VIGOR Study ***replicate and confirm the results of the earlier, still secret Study 090***, but any suggestion that VIOXX was directly responsible for increased cardiovascular episodes jeopardized the drug's commercial viability and the substantial revenue stream it provided to Merck. Nevertheless, contrary to Defendants' misrepresentation that they were "stunned" by the VIGOR Study results, internal Company documents demonstrate that the results ***confirmed what Defendants already knew***: VIOXX increased the risk of heart attacks and cardiovascular disease, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent. According to the November 1, 2004 *Wall Street Journal* article:

> In March 2000, the results of Vigor came in. They showed that Vioxx patients suffered fewer stomach problems than the Naproxen group, but significantly more blood-clot-related problems — precisely the sort of result anticipated in the 1996-97 internal documents. The heart-attack rate in the Vioxx group appeared to be four times as high as the Naproxen group. (Later analysis would show it to be five times as high.) The difference was so wide that Dr. Scolnick, the Merck research chief, appeared to recognize it couldn't come solely from Naproxen's protective effect but must involve some sort of risk inherent in Vioxx. ***In a March 9, 2000, e-mail with the subject line "Vigor," Dr. Scolnick said the results showed that the***

> ***cardiovascular events "are clearly there."*** In an apparent acknowledgement that Vioxx's own mechanism was at least partially at fault for the heart data, he wrote: ***"it is a shame but it is a low incidence and it is mechanism based as we worried it was"*** (emphasis added).

137. In his interview with *60 Minutes*, which was broadcast after the Class Period (on November 14, 2004), Dr. Topol discussed the significance of the VIGOR Study results:

> Whenever you find a problem and you're thinking maybe it's not a problem, you want to see if there's independent replication. So if you have Study 090 and you want to discount that somehow, then you have VIGOR. ***You've got two trials now. You have essentially lightning striking twice. That's independent replication. That's really serious confirmation. This is unequivocal. This is a problem*** (emphasis added).

138. Rather than disclosing the cardiovascular risks of VIOXX, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent, or that that they were "open to the possibility that VIOXX was at fault," Defendants continued to mislead the market by concealing, obscuring, and downplaying the risks, and instead touted VIOXX's purported success. For example, on March 24, 2000 — just fifteen days after defendant Scolnick wrote that the VIGOR results showed that the cardiovascular events "are clearly

there" and "it is mechanism based [*i.e.*, caused by VIOXX] as we worried it was" — Defendants publicly issued Merck's 1999 Annual Report. The cover of the 1999 Annual Report proclaimed: ***"Vioxx: Our biggest, fastest and best launch ever"*** (emphasis added). Defendant Gilmartin stated in his letter to shareholders in the 1999 Annual Report:

> ***Vioxx is the fastest growing prescription arthritis medicine in the United States, and, by the end of 1999, Merck had successfully launched Vioxx in nearly 50 nations*** (emphasis added).

139. Defendants' statements in Merck's 1999 Annual Report were materially false and misleading because, among other things, once Defendants chose to speak about the purported success of VIOXX, they had a duty to speak fully and truthfully and to disclose VIOXX's serious cardiovascular risks, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

140. On March 22, 2000, Defendants filed Merck's 1999 Form 10-K with the SEC. The 10-K was signed by, among others, defendants Gilmartin, Lewent, Henriques, and Scolnick. Defendants stated:

> In May 1999, following a six-month priority review, the FDA cleared VIOXX, Merck's once-daily agent that specifically inhibits COX-2, for relief of the signs and symptoms of osteoarthritis, management of acute pain in adults and treatment of menstrual pain. ***With its product profile for strength, safety and once daily simplicity, VIOXX remains the country's***

> ***fastest growing prescription arthritis medicine.*** In the product's first seven months, U.S. physicians wrote more than five million prescriptions. VIOXX is also enjoying success in the 47 other countries in which it has been launched (emphasis added).
>
> The company is conducting extensive clinical studies with VIOXX to evaluate its efficacy in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease. Merck also has begun studies in patients with colon polyps — a broad population at risk of developing colon cancer. Reducing the number of these polyps may reduce the incidence of colon cancer.

141. The Company's 1999 Form 10-K was materially false and misleading because, among other things, once Defendants spoke about the purported safety, success, and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose VIOXX's serious cardiovascular risks, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

142. Faced with the significant threat to the commercial viability of Merck's multibillion dollar blockbuster drug, Defendants commenced a campaign of misrepresentations and misinformation designed to suppress, obscure, and distort the true safety problems with VIOXX. In sum, Defendants offered the unfounded explanation for the negative findings of the VIGOR Study that: ***the dramatically increased risk of heart***

attacks in persons taking VIOXX was not due to VIOXX; rather, naproxen is cardio-protective and thus reduced the risk of heart attacks. However, naproxen has never been promoted as being cardio-protective. Nor has there even been single clinical or epidemiological (population based) study that supports Defendants' self-serving hypothesis even though naproxen has been available for 25 years and has been used by millions of persons.

143. On March 27, 2000, Defendants issued a Company press release assuring the public that the VIGOR Study did not show that VIOXX caused heart attacks or strokes. Rather, Defendants claimed, although "significantly fewer thromboembolic events were observed in patients taking Naproxen in [the VIGOR Study], ***[that] is consistent with Naproxen's ability to block platelet aggregation .... VIOXX, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects***" (emphasis added). Defendants further stated:

> ***An extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with VIOXX, showed no indication of a difference in the incidence of thromboembolic events between VIOXX, placebo and comparator NSAIDs.*** Further analyses are ongoing, and final results of the GI outcomes study with VIOXX will be presented at peer-reviewed medical meetings this year (emphasis added).

Thus, when faced with evidence that VIOXX posed a significant cardiovascular safety risk, Defendants fabricated the excuse that other drugs were affirmatively "cardio-protective" to mislead the public into believing VIOXX was cardio-neutral as opposed to its true safety profile of cardio-adverse.

144. The March 27, 2000 press release was materially false and misleading because, among other things, it proffered an entirely unfounded explanation for the negative findings of the VIGOR Study with respect to the cardiovascular risks created by VIOXX. By asserting that the reason "significantly fewer thromboembolic events were observed in patients taking Naproxen," as compared to those patients who took VIOXX, was not due to risks associated with VIOXX, but rather was because naproxen was cardio-protective, Defendants sought to conceal the truth: that VIOXX, in fact, had prothrombotic properties, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent. Furthermore, in light of, among other things, the results of Study 090 and the VIGOR Study, Defendants' assurance that, through "an extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with VIOXX," there was "no indication of a difference in the incidence of thrombotic events between VIOXX, placebo and comparator NSAIDs" was an outright lie.

145. Evidencing that the market was, in fact, misled by Defendants' materially false and misleading statements concerning VIOXX's purported safety, success, and prospects for substantial future contributions to Merck's finances, the closing price of Merck common stock rose approximately 4.7% from

$61.13 on March 27, 2000, the day the Company publicly announced the VIGOR Study results, to $64.00 by March 29, 2000.

146. Shortly after materially misrepresenting the significance of the VIGOR Study results to the market, Defendants were informed of the results of another clinical study sponsored by Merck — the "ADVANTAGe Study." Those results demonstrated yet again the significant cardiovascular risks associated with VIOXX.

147. From March 1999 to April 2000, Defendants conducted the ADVANTAGe Study to attempt to demonstrate that VIOXX is less likely to pose GI problems than naproxen. In the ADVANTAGe Study, Merck evaluated the effects of VIOXX (25 mg) versus the effects of naproxen in patients with osteoarthritis. Unlike the VIGOR Study, patients taking low dose aspirin to reduce the risk of heart attack were allowed to participate in the ADVANTAGe Study, thereby masking the actual risk of a cardiovascular event from VIOXX.

148. Although the ADVANTAGe Study **was completed in April 2000, its results were not published until 2003,** when they appeared in the Annals of Internal Medicine.

149. Nevertheless, even after the results were published, Defendants manipulated the published data to conceal the true cardiovascular risks caused by VIOXX. According to a *New York Times* article, entitled "Evidence in VIOXX Suits Shows Intervention by Merck Officials," which was published after the Class Period (April 24, 2005), Defendants distorted the results of the ADVANTAGe Study to conceal the cardiovascular risks associated with VIOXX:

> During the Advantage trial, eight people taking Vioxx suffered heart attacks or sudden cardiac death, compared with just one taking naproxen, according to data released by the F.D.A. earlier this year. The difference was statistically significant, but Merck never disclosed the data that way.

The New York Times article explained that the published results of the ADVANTAGe Study "reported that five patients taking Vioxx had suffered heart attacks during the trial, compared with one taking naproxen, a difference that did not reach statistical significance. ***But the paper never mentioned the three additional cardiac deaths of patients taking Vioxx, including the 73-year-old woman***" (emphasis added).

150. Quoted in *The New York Times* article, Dr. Jeffrey R. Lisse, a rheumatologist at the University of Arizona, who was listed as the study's first author, explained how Defendants were able to conceal the actual results:

> Dr. Lisse said that while he was listed as the paper's first author, Merck actually wrote the report, an unusual practice.
>
> "***Merck designed the trial, paid for the trial, ran the trial***," Dr. Lisse said. "Merck came to me after the study was completed and said, 'We want your help to work on the paper.' The initial paper was written at Merck, and then it was sent to me for editing."

> Dr. Lisse said he had never heard of the case of the woman who died, until told of it by a reporter. ***"Basically, I went with the cardiovascular data that was presented to me,"*** he said (emphasis added).

151. The April 24, 2005 *New York Times* article reported that Defendants were fearful that truthful disclosure of the actual results of the ADVANTAGe Study would threaten VIOXX's commercial success:

> Back in 2000, Merck was already struggling to explain the results of another study, called Vigor, which also indicated that patients taking Vioxx had more heart attacks than those taking naproxen, which is found in over-the-counter drugs like Aleve. Unlike the Advantage results, the Vigor results had been publicly disclosed by Merck.
>
> ***Dr. Scolnick expressed his worry in e-mail messages to other senior Merck scientists that the Advantage results would encourage the F.D.A. to demand that Vioxx's label highlight its cardiac risks. Such a change would have damaged Vioxx's sales, especially because a competing drug, Celebrex, did not have heart risks prominently displayed on its warning label.***
>
> In e-mail messages on April 7, 2001, to Dr. Douglas A. Greene, an executive vice president at Merck Research

> Laboratories, ***Dr. Scolnick wrote that he was especially angry because the Advantage trial had no scientific purpose.*** In theory, Merck set up the trial to show that Vioxx caused fewer stomach problems than naproxen. But Merck had already demonstrated that with the Vigor trial, which tracked more than 8,000 patients for a year.
>
> As it turned out, Merck's marketing department had created the Advantage trial as a promotional tool, to introduce about 600 doctors to Vioxx. ***"This course is just stupid," Dr. Scolnick wrote. "Small marketing studies which are intellectually redundant are extremely dangerous"*** (emphasis added).

152. The article elaborated further on Defendants' successful efforts to manipulate and conceal the ADVANTAGe Study's results:

> In 1998, Merck had created a committee of academic researchers to review the case reports for many patients who had suffered suspected heart problems in clinical trials of Vioxx and Arcoxia, a Merck arthritis drug that has still not been approved. But the woman's case never reached the outside committee because the cause of death listed on the death certificate from an independent autopsy — hypertensive heart disease — did not fall into a category that would automatically prompt Merck to refer the case.

> As a result, Merck reviewed the case internally. After examining the case, Dr. Eliav Barr, a Merck scientist, initially judged that the woman had probably died of a heart attack.
>
> "Common things being common, the clinical scenario is likely to be MI," Dr. Barr wrote in an e-mail message in November 2000 to Dr. Reicin, the clinical research executive. MI is an abbreviation for myocardial infarction, or heart attack. "Certainly, it is not definitive. I just used my clinical judgment."
>
> Dr. Reicin quickly responded, "I think this should be called an unknown cause of death." A few hours later, she wrote, "***I would prefer unknown cause of death so we don't raise concerns***" (emphasis added).

153. Subsequent to the April 24, 2005 *New York Times* article, on May 2, 2005, *Bloomberg News*, in an article entitled "Merck Study May be Corrected, Annals of Internal Medicine," reported: "[T]he Annals of Internal Medicine may publish a correction to a Merck [] sponsored study of the pain pill Vioxx to show the drug had a higher risk of heart attacks than originally stated."

154. In response to the April 24, 2005 *New York Times* article, Harold Sox, journal editor for the *Annals of Internal Medicine*, stated in an April 27, 2005 interview with *Bloomberg News*:

> ***Corrections happen all the time, but corrections that materially change the***

> ***message of the article are pretty uncommon . . . If they had told us it was 8-to-1, it would have been much different than 5-to-1*** (emphasis added).

155. *Bloomberg News* also reported: "Sox said he learned that the trial results he published might have been manipulated when he opened his *New York Times* on April 24 [2005.] He met with his editorial staff the following day and posted a notice on the magazine's web site notifying readers the staff was considering a correction."

156. On April 24, 2000, Defendants issued a Company press release announcing Merck's financial results for the first quarter 2000, the period ending March 31, 2000. Defendant Gilmartin commented on the Company's performance:

> ***Sales growth for the quarter was led by VIOXX, the fastest growing prescription arthritis medicine in the United States,*** other newer and established products and growth from the Merck-Medco Managed Care business (emphasis added).
>
> Five key products — VIOXX, ZOCOR, FOSAMAX, SINGULAR, and COZAAR/HYZAAR(1) — led Merck's growth, and account for more than 50% of Merck's worldwide human health sales.

Defendants also stated:

> VIOXX remains the fastest growing prescription arthritis medicine in the United States. More than 9 million

> prescriptions have been written for VIOXX since its U.S. introduction 10 months ago. In addition, it is the only medicine specifically inhibiting COX-2 that is indicated both for treatment of osteoarthritis and for relief of acute pain, such as pain following knee, hip replacement and dental surgery. VIOXX is enjoying strong success in the European countries where it has been launched, including the United Kingdom, Germany and Spain. In all, VIOXX has been launched in more than 50 countries.
>
> ***Merck is conducting extensive clinical studies with VIOXX to evaluate its efficacy in the treatment of rheumatoid arthritis and in the prevention and treatment of Alzheimer's disease***. Merck has also begun studies to investigate whether VIOXX can reduce the number of colon polyps in patients who suffer from them — a broad population at risk of developing colon cancer (emphasis added).

157. The April 24, 2000 press release was materially false and misleading in that, among other things, once Defendants chose to speak about the "sales growth" and potential expansion of the uses of VIOXX, they had a duty to speak fully and truthfully and to disclose VIOXX's adverse cardiovascular safety profile, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

158. Later that day, Defendants held a conference call for analysts, money and portfolio managers, institutional investors, and large Merck shareholders. During the call, Laura Jordan, Merck's Senior Director of Investor Relations, commented on VIOXX's purported success:

> On a weekly basis, approximately 200,000 new prescriptions are written for VIOXX in the US. That's up from the approximately 160,000 weekly new prescriptions that I reported to you in last quarter's call. Total prescriptions on a weekly basis currently running about 350,000 per week, total prescriptions. That's up from the approximately 260,000 weekly total prescriptions I reported to you on our last call. Looking at our cumulative U.S. VIOXX prescription since we launched, looking at it through the end of last week, nearly 10 million prescriptions had been written for VIOXX in the U.S. and of course, that number continues to grow on a daily basis.
>
> So as you can see the Vioxx launch continues to meet the very robust expectations that we had for the product and as most of you know we continue to conduct extensive clinical studies with Vioxx to evaluate its expectancy in Alzheimer's disease, rheumatoid arthritis, and colonic polyp[s.]

159. Defendants' statements during the conference call were materially false and misleading

because, among other things, once Defendants chose to speak about the purported success and advantages of VIOXX, and its prospects for expanded use to treat other ailments, they had a duty to speak fully and truthfully, and to disclose the serious cardiovascular risks associated with VIOXX which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

160. During the Class Period, as part of their effort to obscure, discredit, and suppress any information concerning the cardiovascular risks posed by VIOXX, Defendants, among other things, falsely assured the public that VIOXX was safe. For example, on April 27, 2000, *Reuters* reported securities analysts' speculation that the VIGOR Study results might trigger regulatory scrutiny of VIOXX. *Reuters*, however, also reported that the day before, in anticipation of the *Reuters* April 27 report, Merck spokesperson Jan Weiner had told *Reuters* that there was no evidence VIOXX actually put patients at greater risk of any adverse cardiovascular event than did naproxen, and that naproxen provided protection to patients taking it.

161. On April 28, 2000, Defendants, through a Company press release, moved quickly to "confirm [] the favorable cardiovascular safety profile of VIOXX," and allay any concerns in the market due to the *Reuters* report. Defendants' April 28 press release represented:

> Extensive review of data from the completed osteoarthritis trials and on-going clinical trials with Vioxx, as well as post-marketing experience with Vioxx have shown ***NO DIFFERENCE*** in the incidence of cardiovascular events, such as heart attacks, among patients taking

> Vioxx, other NSAIDs and placebo. [Emphasis in original.]

162. Defendants' April 28, 2000 press release was materially false and misleading in that, among other things, it falsely represented that clinical trials showed there was no cardiovascular risk due to VIOXX and failed to disclose the truth with respect to VIOXX's adverse safety profile. As the results of clinical trials conducted by Defendants, which are discussed above, including Study 090, the VIGOR Study, and the ADVANTAGe Study, made clear, the statement that "clinical trials with Vioxx, as well as post-marketing experience with Vioxx have shown ***NO DIFFERENCE*** in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx, other NSAIDs and placebo" was utterly false.

163. That the market continued to be misled by Defendants' false assurances concerning the safety, success, and future commercial expansion and viability of VIOXX is further evidenced by the comments of securities analysts who followed Merck. For example, on April 28, 2000, Tony Butler, an analyst at Lehman Brothers, issued a report, which stated:

> Concerns have been circulated in the press that Merck's Cox-2 inhibitor drug, VIOXX, may be associated with increased risk of stroke or heart attack. These concerns are not supported by the clinical data publicly known.
>
> In our March 27 note, we wrote that Merck's preview of the VIGOR study results included a statistically significant

> differential in thromboembolic events between VIOXX and Naproxen users. ***Merck attributes the difference to Naproxen's platelet blocking characteristics*** (emphasis added).

164. Further reflecting the market's acceptance of Defendants' false assurances regarding VIOXX, on April 28, 2000, Neil Sweig, an analyst with Ryan, Beck, & Co., commented: ***"There is no credibility problem for Merck."*** (Emphasis added.)

165. Similarly, on May 1, 2000, Bernstein Research Call issued an analyst report that stated: "We'd be shocked if [the] FDA gave this a second glance, much less re-labeled VIOXX to suggest greater risks of vascular events. It's not VIOXX increasing events, it's Naproxen reducing them" (emphasis in original). Thus, Defendants' recasting of VIOXX as cardiovascular neutral by falsely characterizing naproxen as cardioprotective had succeeded in concealing, distorting, and obscuring the true safety risks of VIOXX from the market, and thus continued to protect Merck's VIOXX franchise and its consequent revenue stream for the Company.

166. An article appearing in the May 3, 2000 *Pharma Marketletter* further illustrated Defendants' efforts to discredit, obscure, and suppress the truth. The *Pharma Marketletter* noted that preliminary data from the VIGOR Study "may mean [Merck] will be questioned by the [FDA], according to CNBC and Reuters reports." The *Pharma Marketletter*, reported, however, that ***"in a statement, Merck said that 'in response to speculative news reports . . . it confirms the favorable cardiovascular profile of VIOXX.'"*** (Emphasis added).

Defendants went on to claim that a review of data shows ***"no difference in the incidence of cardiovascular events...among patients taking Vioxx, other NSAIDs and placebo"*** (emphasis added). Again, as demonstrated above, this was false.

167. Defendants' unqualified assurances regarding the safety of VIOXX, as quoted by *Pharma Marketletter*, were materially false and misleading in light of the truth regarding the serious cardiovascular risks associated with VIOXX.

168. On or about May 12, 2000, Defendants filed with the SEC Merck's Form 10-Q for the first quarter of 2000. The Form 10-Q was signed by defendants Frazier and Henriques. The Form 10-Q repeated the same materially false and misleading statements concerning the purported success and safety of VIOXX that were made in Merck's April 24, 2000 press release referred to above.

169. An internal Company email, dated May 25, 2000, from Margie McGlynn, a Merck employee who worked in the Worldwide Human Health Marketing Department, to defendant Reicin (which cc'd defendant Scolnick), demonstrates the success of Defendants' efforts to manipulate the information that securities analysts disseminated publicly in their reports. In the email, entitled "VIGOR Analyst Reports," McGlynn stated:

> ***Alice, attached are 2 analyst reports which most clearly demonstrate the success of our efforts <u>to defuse the CV risk issue for VIOXX</u>***. You played a major role in making this happen, along with Brian and I know many others supporting

> you in MRL. I wanted to personally thank you for all of your efforts and the tremendous support you provided for the marketing organization (emphasis added).

170. The analyst reports that were attached to the May 25, 2000 email evidence that Defendants succeeded in misleading securities analysts, as well as investors, with respect to the results of the VIGOR Study. According to the Deutsche Bank. Alex. Brown analyst report, dated May 24, 2000:

> After attending the presentation of VIGOR trial data at DDW in San Diego, we highlight the following key points:
>
> * * *
>
> "NO DIFFERENCE FROM CELEBREX IN CARDIO EVENTS . . . [Emphasis in original] Responding directly to recent comparisons with Celebrex which questioned Vioxx's cardiovascular safety profile, the VIGOR data demonstrated that there was no difference in cardiovascular mortality and the incidence of strokes between the groups treated with naproxen and Vioxx. Significantly fewer heart attacks were seen in patients taking naproxen (0.1 percent) compared to the group taking Vioxx (0.4 percent), ***which appears to be consistent with naproxen's ability to block platelet aggregation by inhibiting COX-1.*** In fact, 4 percent of the patients enrolled in VIGOR did meet the criteria for use of aspirin to prevent

> second cardiac events, but were not permitted to take aspirin in the trial. Therefore, among the remaining 96 percent of patients in VIGOR, there was no statistical difference in heart attack rates: 0.1 percent for naproxen, and 0.2 percent for Vioxx. Vioxx's 0.2 percent event rate was the same rate as reported for Celebrex in non-aspirin patients in the CLASS trial. In the Celebrex trial, the patients were at risk were allowed to take aspirin. Moreover, in other completed OA trials, Vioxx demonstrated no difference in the incidence of cardiovascular events vs. ibuprofen and diclosfenac, the same NSAIDs used in the Celebrex CLASS trial (emphasis added).

171. On June 29, 2000, Defendants issued a Company press release announcing that Merck "today had submitted a Supplemental New Drug Application for VIOXX" to the FDA seeking to "request labeling changes based on the recently completed 8,000-patient ***gastrointestinal outcome study*** called VIGOR" (emphasis added). Defendants' press release was materially false and misleading because it failed to disclose and misrepresented that: (i) VIOXX created an increased risk of heart attack; and (ii) Defendants' explanation for the negative results of the VIGOR trial with respect to the adverse cardiovascular events suffered by individuals who took VIOXX was unfounded.

172. The following day, Merck common stock jumped from $74.11 to close at $76.63 per share.

173. On July 24, 2000, Defendants issued a Company press release announcing Merck's financial results for the second quarter 2000, the period ending June 30, 2000. Defendant Gilmartin commented on the Company's performance:

> Sales growth for the quarter and the first half of 2000 was led by VIOXX, the other newer and established products and growth from the Merck-Medco Managed Care business.

Commenting on Merck's five key products, which included VIOXX, defendant Gilmartin noted:

> The five products provide a strong platform for growth.... Each is a successful . . . medicine, ***offering a unique competitive advantage in the market***, and we are conducting additional clinical studies that will potentially extend each franchise to even more patients (emphasis added).

174. The July 24, 2000 press release also stated:

> In May, Merck presented results from the 8,000 patient VIOXX Gastrointestinal Outcomes Research (VIGOR) study in which VIOXX reduced the incidence of serious gastrointestinal side effects, such as ulcers and bleeding, by more than 50 percent compared to the nonsteroidal anti-inflammatory drug Naproxen. In June, Merck submitted a Supplemental New Drug Application for VIOXX to the U.S. Food and Drug Administration (FDA) to

> request labeling changes based on the study.

175. The July 24, 2000 press release was materially false and misleading because, among other things, it failed to disclose and misrepresented that: (i) VIOXX created a significant risk of heart attack for its users; (ii) Defendants' explanation for the negative results of the VIGOR trial with respect to the adverse cardiovascular events suffered by individuals who took VIOXX was entirely unfounded; and (iii) VIOXX did not offer a "unique competitive advantage" given that, in truth, VIOXX created a serious cardiovascular risk and provided no greater efficacy than its competitors. In addition, once Defendants chose to speak about the purported success and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

176. Also on July 24, 2000, subsequent to the release of the financial results for the second quarter of 2000, Merck held a conference call for analysts, money and portfolio managers, institutional investors, and large Merck shareholders. During the call, Laura Jordan, Merck's Senior Director of Investor Relations, commented on VIOXX's purported continued growth in sales:

> Let's start with VIOXX, Merck's Cox-2 inhibitor for osteoarthritis and pain, second quarter sales on a worldwide basis for VIOXX were $475 million and VIOXX has now become one of Merck's largest

> selling products, in fact, we sold more VIOXX this quarter than we've sold in all of 1999.
>
> ***[T]he VIOXX launch continues to meet the very robust expectations that we've had for the product. We continue to be extremely pleased with this uptake in the marketplace in countries throughout the world. We're extremely pleased with the acceptance by physicians, patients and payors, and we are very bullish on the product's future growth and prospects*** (emphasis added).

177. Defendants' statements during the conference call were materially false and misleading because, among other things, once Defendants chose to speak about the purported success and advantages of VIOXX, they had a duty to speak fully and truthfully, and to disclose the serious cardiovascular risks associated with VIOXX, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent. Such truthful disclosure would have flatly, negated Defendants' representations about the "acceptance" of VIOXX "by physicians, patients and payors," who were unaware of the cardiovascular safety risks of VIOXX, and Defendants being "bullish on the product's future growth and prospects," because those "future growth and prospects" depended on concealing, misrepresenting, distorting, and obscuring the drug's true safety profile.

178. On August 10, 2000, Defendants filed Merck's Form 10-Q for the second quarter 2000, which

was signed by defendants Frazier and Henriques. The Form 10-Q repeated the materially false and misleading statements Defendants made in the July 24, 2000 press release, as set forth above.

179. Defendants' success in portraying VIOXX as superior to its competitors and having a risk-free safety profile misled securities analysts to issue highly positive reports concerning the drug, and the Company's performance and prospects. For example, a July 25, 2000 Sutro & Co. analyst report stated:

> We are upgrading our rating from Hold to Accumulate and increasing our price target from $80 to $85. ***VIOXX is doing much better than we had anticipated and this has caused us, along with the rest of the Street to raise EPS estimates*** (emphasis added).

Had the market, in particular securities analysts, been aware of the falsity of Merck's competitive claims, and the true safety risks of VIOXX, they would not have reported positively on Merck.

180. On or about October 20, 2000, Defendants issued a Company press release announcing the Company's financial results for the third quarter 2000, the period ending September 30, 2000. Defendant Gilmartin commented on the Company's performance:

> Income growth for the quarter and first nine months reflects strong sales volume gains in the U.S. and international markets, as well as manufacturing productivity improvements .... These gains helped fund research and

development and promotion programs in support of our key products.

We are proud of the achievements of our newest medicine VIOXX which, together with Zocor, Cozzaar/Hyzaar*, Fosamax, and Singulair are driving Merck's strong performance.

Not only are Merck's medicines achieving success in markets in the United States and abroad, they are also improving the lives of millions of patients worldwide. . . . More than 15 million prescriptions in the United States alone have been written for VIOXX, our new medicine for osteoarthritis, since its extraordinarily successful launch last year, and it continues as the world's fastest growing prescription arthritis medicine. VIOXX has now achieved nearly $1.5 billion in sales so far this year — more than $600 million in this quarter alone.

181. In addition, Defendants' October 20, 2000 press release stated:

A pilot study in osteoarthritis comparing VIOXX and celecoxib, a competitive product, presented at the European League Against Rheumatism in June, showed that VIOXX reduced osteoarthritis pain at night and at rest to a greater degree than either celecoxib 200 mg or acetaminophen 4,000 mg.

> In June, Merck submitted a Supplemental New Drug Application for VIOXX to the FDA to request labeling changes based on the results of the 8,000-patient VIOXX Gastrointestinal Outcome Research (VIGOR) study. In this study, VIOXX reduced the incidence of serious gastrointestinal side effects, such as ulcers and bleeding, by more than 50% compared to the nonsteroidal anti-inflammatory drug Naproxen.

182. Defendants' October 20, 2000 press release was materially false and misleading because, among other things, it misrepresented and failed to disclose that (i) VIOXX created an increased risk of heart attacks; and (ii) Defendants' explanation for the negative results of the VIGOR trial with respect to the adverse cardiovascular events suffered by individuals who took VIOXX was entirely unfounded. In addition, once Defendants chose to speak about the purported safety, success, and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

183. In November 2000, the VIGOR Study results were published in the *New England Journal of Medicine*, by academics retained by Merck. The November 2000 article — much like the Merck-sponsored Holt seminars in June 2000 discussed above — emphasized VIOXX's purported GI benefits and downplayed the cardiovascular risks. The November 2000 article concluded:

> In patients with rheumatoid arthritis, treatment with [VIOXX], a selective inhibitor of cyclooxygenase-2, is associated with significantly fewer clinically important upper gastrointestinal events than treatment with naproxen, a nonselective inhibitor.

Merck's retained academics falsely reported that VIOXX did not show a significant rise in heart attacks and did not provide detailed information about other serious cardiovascular complications such as strokes or blood clots.

184. On or about November 13, 2000, Defendants filed Merck's Form 10-Q for the third quarter 2000, the period ending September 30, 2000, which was signed by defendants Frazier and Henriques. The Form 10-Q repeated the false and misleading statements Defendants made in the October 20, 2000 press release, as set forth above.

185. Again evidencing the success of Defendants' effort to mislead the market with respect to the safety and success of VIOXX, Merck common stock reached a Class Period high, closing price of $94.88 on November 29, 2000.

186. On December 12, 2000, Defendants issued a Company press release that addressed Merck's Annual Business Briefing, which was held that day with over 300 securities analysts in attendance. The press release quoted defendant Gilmartin's comments during the Business Briefing: "***Merck has created a strong platform for growth and is delivering outstanding performance***" (emphasis added). In fact, that "platform" was built on a tissue of lies, and omissions concerning the

competitive advantages of VIOXX and its true safety profile.

187. The December 12, 2000 press release, and defendant Gilmartin's comments to securities analysts, were materially false and misleading because, among other things, Defendants failed to disclose that VIOXX, Merck's second best selling drug, which accounted for more than $2.16 billion in revenue and almost 10% of all Merck pharmaceutical sales in 2000, significantly increased the risk of heart attack, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

188. On January 23, 2001, Defendants issued a press release announcing Merck's financial results for the fourth quarter and full year 2000, the periods ending December 31, 2000. Defendant Gilmartin commented on the Company's performance:

> ***Our five key products, VIOXX, ZOCOR, COZAAR/HYZAAR*, FOSAMAX and SINGULAIR, drove Merck's performance for the year and created a powerful platform for growth.***
>
> ***Each of the five medicines offers unique competitive advantages.*** . . . VIOXX, a once-a-day medicine, is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. Since its extraordinarily successful 1999 launch, VIOXX has become the world's fastest growing branded prescription arthritis medicine, and it is already Merck's second largest-selling medicine. In the United States, VIOXX now accounts for

> approximately 50 percent of new prescriptions in the COX-2 class (emphasis added).

The press release also stated:

> A Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for Feb. 8 to review labeling changes Merck has requested based on the strong results of the VIGOR Study. This 8,000-patient gastrointestinal outcomes research study, ***in which VIOXX reduced the risk of serious gastrointestinal complications by half compared to the NSAID Naproxen***, was published in November in the New England Journal of Medicine (emphasis added).

189. The January 23, 2001 press release was materially false and misleading because it failed to disclose and misrepresented that: (i) VIOXX created an increased risk of heart attack; and (ii) Defendants' explanation for the negative results of the VIGOR trial with respect to the adverse cardiovascular events suffered by individuals who took VIOXX was unfounded. In addition, once Defendants chose to speak about the purported success of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

190. On February 8, 2001, Defendants issued a Company press release announcing, among other things,

that the FDA Arthritis Advisory Committee met that day to review Merck's application to modify the prescribing information for VIOXX to reflect results of the VIGOR Study. Commenting on the data that Defendants submitted to the FDA Advisory Committee, Eve Slater, M.D., Merck's Senior Vice President, Clinical and Regulatory Development, stated: ***"Merck is confident that the data presented today support the excellent safety profile of VIOXX"*** (emphasis added).

191. The February 8, 2001 press release was materially false and misleading in that the "safety profile of VIOXX" was hardly "excellent" in light of the significantly increased risks of cardiovascular problems caused by the drug. Indeed, Defendants knew the opposite to be true.

192. As part of their effort to mislead the public with regard to the safety of VIOXX, beginning, at least as early as March 2001, and continuing throughout the Class Period, Defendants ran national television and print advertisements that failed to make any mention whatsoever of the serious cardiovascular risks associated with VIOXX, and instead emphasized the purported benefits of the drug.

193. On or about March 23, 2001, Defendants filed with the SEC Merck's Form 10-K for 2000, the period ending December 31, 2000. The Form 10-K, which was signed by, among others, defendants Gilmartin, Lewent, Henriques, and Scolnick, stated:

> Vioxx, Merck's newest medicine for the treatment of osteoarthritis and acute pain, has become the world's fastest growing branded prescription arthritis medicine and is already Merck's second largest-

selling product. In the United States, Vioxx now accounts for approximately 50% of new prescriptions in the COX-2 class, despite being second to market. Vioxx is the only COX-2 inhibitor in the United States both for osteoarthritis and acute pain. In May 2000, Merck presented results from an 8,000 patient Vioxx Gastrointestinal Outcomes Research (VIGOR) study, which was subsequently published in the New England Journal of Medicine, in which Vioxx reduced the incidence of serious gastrointestinal side effects, such as ulcers and bleeding, by more than 50% compared to the nonsteroidal anti-inflammatory drug naproxen. In June 2000, the Company submitted a supplemental New Drug Application to the FDA to request label changes to reflect the results of this study. In February 2001, an FDA Arthritis Advisory Committee recommended that the gastrointestinal study results, as well as data on certain cardiovascular events, be included in the labeling; the FDA is not obligated to accept the recommendations of its advisory committees. In November 2000, another study showed that Vioxx significantly reduced moderate-to-severe acute pain caused by dental surgery to a greater degree compared to codeine combined with acetaminophen. Merck continues to conduct clinical trials with Vioxx to evaluate its efficacy in the treatment of rheumatoid arthritis and the

> prevention and treatment of Alzheimer's disease as well as investigating whether Vioxx can reduce the number of colon polyps in patients who suffer from them — a broad population at risk of developing colon cancer.

194. The 2000 Form 10-K was materially false and misleading in that Defendants misrepresented and concealed the truth concerning the safety of VIOXX, and the results of the VIGOR Study. Additionally, Defendants once again touted the broad potential uses for VIOXX without disclosing the serious adverse health risks attendant to the drug. Once Defendants chose to speak about the purported safety, success and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose the serious cardiovascular risks, which jeopardized VIOXX's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

195. On March 30, 2001, Defendants issued Merck's 2000 Annual Report, which stated that "***[a]ll the vital information about how your Company fared in 2000 is in your hand***" (emphasis added), or accessible on Merck's website (Defendants provided the "link address" for this additional information). In the 2000 Annual Report, Defendants commented on the purported success of VIOXX and its ability to generate substantial revenues over the life of Merck's patent:

> When we find a molecule that holds promise of becoming a commercially viable medicine capable of bringing real value to patients, it receives significant company resources. VIOXX and Cancidas are just

> two of our more recent drugs to spring from this approach. ***VIOXX is a blockbuster with global sales topping $2 billion in a mere 20 months.*** Cancidas, just launched in February 2001, may never be a blockbuster of this magnitude, but it is vitally needed by patients. . . (emphasis added).

In the 2000 Annual Report, defendant Scolnick also made the following comments:

> The number of compounds brought into development over the past three years far exceed the total in any preceding three-year period. ***And those compounds possess better qualities than any of their predecessors brought forward in a like time span because we have been able to analyze and test them in more detail.***
>
> * * *
>
> ***The result of [Merck's] behavior is a vibrant company delivering to shareholders the returns they expect with an ethic that always puts patients first*** (emphasis added).

196. The 2000 Annual Report was materially false and misleading because, among other things, once Defendants chose to speak about the purported success and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose the serious cardiovascular risks associated with VIOXX, which jeopardized its

commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

197. On April 10, 2001, Defendants issued a Company press release, which reported that Merck had received a letter from the FDA relating to the Company's application for changes to the prescribing information for VIOXX. Defendants again expressed their confidence "in the comprehensive data that support the excellent gastrointestinal and ***overall safety profile of VIOXX***" (emphasis added).

198. Defendants' unqualified assurances concerning the "safety profile of VIOXX" were materially false and misleading in light of the truth regarding the serious cardiovascular risks associated with VIOXX.

199. On April 20, 2001, Defendants issued a Company press release announcing Merck's financial results for the first quarter 2001, the period ending March 31, 2001. Defendant Gilmartin commented on the Company's performance:

> Income growth for the quarter reflects strong worldwide sales volume gains led by our five key growth drivers — ZOCOR, VIOXX, COZAAR and HYZAAR*, FOSAMAX and SINGULAIR — which combined had increased sales of 30% over first quarter 2000 sales.

Defendants also stated:

> VIOXX, a once-a-day medicine, is the only COX-2 selective agent indicated in the United States for both osteoarthritis and acute pain. ***Since its successful 1999***

> ***launch, VIOXX has become the world's fastest-growing branded prescription arthritis medicine, and it is already Merck's second largest selling medicine. VIOXX achieved $485 million in sales for the first quarter 2001*** (emphasis added).

200. The April 20, 2001 press release was materially false and misleading because it failed to disclose and misrepresented that: (i) VIOXX created an increased risk of heart attacks; and (ii) Defendants' explanation for the negative results in the VIGOR trial with respect to the adverse cardiovascular events suffered by individuals who took VIOXX was unfounded. In addition, once Defendants chose to speak about the purported success and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks, which jeopardized VIOXX's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

201. On or about May 10, 2001, Defendants filed with the SEC Merck's Form 10-Q for the first quarter 2001. The 10-Q was signed by defendants Frazier and Henriques, and contained the same materially false and misleading statements concerning the purported success and advantages of VIOXX that were made in the Company's April 20, 2001 press release referred to above.

202. On May 22, 2001, Defendants issued a Company press release, which stated, among other things: ***"In response to news and analyst reports of data the Company first released a year ago, Merck & Co., Inc. today reconfirmed the favorable***

cardiovascular safety profile of VIOXX" (emphasis added).

203. The representation in the May 22, 2001 press release regarding Merck confirming the "***favorable cardiovascular safety profile of VIOXX***" (emphasis added) was materially false and misleading because patients taking VIOXX had a significantly increased incidence of serious cardiovascular problems.

204. On May 28, 2001, Defendants issued another Company press release, which again "***reconfirmed the favorable cardiovascular safety profile of VIOXX***" (emphasis added). This representation in the May 28, 2001 press release stating that the "***favorable cardiovascular safety profile of VIOXX***" was "***reconfirmed***" (emphasis added) was materially false and misleading because Defendants knew that patients taking VIOXX had a significantly increased incidence of serious cardiovascular problems.

205. On June 13, 2001, Defendants issued a Company press release announcing, among other things: "In a new meta-analysis combining data from 19 clinical studies with VIOXX (rofecoxib) involving more than 28,000 patients, ***the relative risks of serious cardiovascular events were similar with VIOXX and placebo, and with VIOXX and the widely prescribed non-steroidal anti-inflammatory drugs (NSAIDs) ibuprofen, dicofenac and nabumetone.***" (emphasis added).

206. The press release quoted defendant Reicin:

> Results seen in the meta-analysis with VIOXX vs. naproxen are consistent with the ability of naproxen to block platelet

> aggregation, and, therefore, to act as an anti-platelet agent.

207. The June 13, 2001 press release was materially false and misleading because it: (i) failed to disclose and misrepresented that VIOXX posed a significant risk of serious cardiovascular events that was greater than the risks posed by other NSAIDs or placebo, and (ii) provided an entirely unfounded explanation for the lower incidence of adverse cardiovascular events among patients taking naproxen.

208. On July 20, 2001, Defendants issued a Company press release announcing Merck's financial results for the second quarter 2001, the period ending June 30, 2001. Defendant Gilmartin commented on the Company's performance:

> Income growth for the first six months reflects strong worldwide sales volume gains led by our five key growth drivers [ZOCOR, VIOXX, COZAAR/HYZAAR, FOSAMAX and SINGULAIR], which combined increased 28% over the first six months 2000 sales.

Defendants also stated:

> In 2001, Vioxx achieved new-prescription leadership within the coxib market in the United States, ***demonstrating that physicians continue to recognize the medicine's benefits to the patients.***
>
> ***New scientific data supporting the efficacy and overall safety profile of VIOXX were presented at medical***

> ***meetings during the quarter. These data included the results of the ADVANTAGe trial, presented at the Digestive Diseases Week conference in May*** (emphasis added).

209. The July 20, 2001 press release was materially false and misleading because, among other things, it failed to disclose that VIOXX had "achieved new-prescription leadership within the coxib market" as a result of Defendants' scheme to have their sales representatives mislead physicians about VIOXX's safety profile. The press release was also materially false and misleading because it misrepresented and failed to disclose that the results of the ADVANTAGe Study did not confirm the overall safety profile of VIOXX, but rather confirmed that VIOXX was associated with serious cardiovascular risks. In addition, once Defendants chose to speak about the purported safety, success, and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose the serious cardiovascular risks associated with VIOXX, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

210. Also on July 20, 2001, subsequent to the release of the financial results for the second quarter of 2001, Merck held a conference call for analysts, money and portfolio managers, institutional investors, and large Merck shareholders. During the call, Laura Jordan, Merck's Senior Director of Investor Relations, commented on VIOXX's purported continued growth in sales:

So let's start with the first product on your sheet, VIOXX, which as you all know is Merck's Cox-2 inhibitor for osteoarthritis and pain. Second quarter 2001 sales of VIOXX on a worldwide basis were $725 million, up 53% over second quarter last year and year-to-date Vioxx sales were $1.2 billion, that's up 43% six months year-to-date this year over six months year-to-date last year.

* * *

Vioxx continues to show strong growth. As we talked about many times in the past, it's prescriptions that reflect the true underlying demand of a product and the fundamental business or the prescription trends for Vioxx remain quite healthy. In fact, total prescriptions year-to-date through June for Vioxx are up 41% and new prescriptions are up nearly 25%. All of this is clearly in line with the year-to-date sales growth for the product in the US of +33%. Hoping to fuel this growth in Vioxx are the additional sales reps that I mentioned earlier. We now have 1,000 more voices describing the product's benefits to the marketplace and clearly that's helping to continue to fuel the growth. In terms of future sales of Vioxx, the worldwide growth sales forecast that was provided on June 22nd, of $3 billion to $3.5 billion still holds (emphasis added).

211. Defendants' statements during the conference call were materially false and misleading because, among other things, once Defendants chose to speak about VIOXX's "sales growth," they had a duty to speak fully and truthfully and to disclose the serious cardiovascular risks attributable to the drug, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent. In addition, Defendants' statement concerning the "***1,000 more voices [of Merck's VIOXX sales representatives] describing the product's benefits to the marketplace***" (emphasis added) was materially false and misleading because, as alleged herein, Defendants had trained Merck's VIOXX sales representatives to conceal the cardiovascular risks of the drug from physicians and the market.

212. On or about August 10, 2001, Defendants filed with the SEC Merck's Form 10-Q for the second quarter 2001. The Form 10-Q was signed by defendants Frazier and Henriques, and contained essentially the same materially false and misleading statements concerning the purported safety, success, and advantages of VIOXX that were made in Merck's July 20 press release referred to above.

213. On August 22, 2001, *JAMA* published an article, authored by cardiologists Eric J. Topol, Steven E. Nessen, and Debabrata Mukherjee of the Cleveland Clinic, entitled "*Risk of Cardiovascular Events Associated With Selective COX-2 Inhibitors*," which reported the results of a study of VIOXX and Celebrex (the "Cleveland Clinic Study"). The *JAMA* article reported the findings of the Cleveland Clinic Study that "[c]urrent data would suggest that use of selective COX-2 inhibitors might lead to increased cardiovascular

events." The article also noted: "The available data raise a cautionary flag about the risk of cardiovascular events with COX-2 inhibitors."

214. On August 21, 2001, the day before the *JAMA* article was published, *Bloomberg News* reported that, in anticipation of the publication of the Cleveland Clinic Study findings, Merck, through its Senior Director of Cardiovascular Clinical Research, Laura Demopoulos, commented: "***We already have additional data beyond what they cite, and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo***" (emphasis added). According to the authors of the *JAMA* article, however, the Cleveland Clinic Study was based, in part, on Merck's own data.

215. Defendants not only disparaged the Cleveland Clinic's findings prior to their release, asserting falsely that Merck "already [had] additional data beyond what" the Cleveland Clinic cited which was "very, very reassuring" that "VIOXX [did] not result in any increase in cardiovascular events compared to a placebo," but, according to a *Wall Street Journal* article, dated August 22, 2001, Defendants previously had taken affirmative steps to suppress publication of the Cleveland Clinic Study results. According to *The Wall Street Journal* article, the *JAMA* article's "release follows an unusual behind-the-scenes push by [Merck] to lobby the prominent cardiologists who wrote the study and the journal that published it. . . . Merck sought to downplay the cardiac issue – in meetings in New York and Cleveland with Cleveland Clinic Doctors, in e-mails and in phone calls to the Cleveland doctors and the editor of JAMA."

216. Also, according to *The Wall Street Journal*, Merck's Vice President of Medical Communications, Laurence Hirsch, asked *JAMA* to carry a rebuttal article to accompany the publication of the Cleveland Clinic's findings. *The Wall Street Journal* quoted Dr. Topol, one of the *JAMA* article's authors: ***"It was quite extraordinary and almost humorous that the company would do this"*** (emphasis added).

217. In addition, on August 23, 2001, the day after the release of the *JAMA* article, Defendants continued to stonewall by stating in a Company press release ***"the Company stands behind the overall and cardiovascular safety profile . . . of VIOXX"*** (emphasis added).

218. Immediately after the publication of the *JAMA* article, Defendants sent, ***by Federal Express***, "Dear Doctor" letters to physicians throughout the country disparaging the article as ***"not based on any new clinical study"*** and assuring the physicians that Merck ***"stands behind the overall and cardiovascular safety profile"*** of VIOXX (emphasis added).

219. The August 23, 2001 press release and the "Dear Doctor" letters were materially false and misleading in that they misrepresented and failed to disclose the truth regarding the adverse safety profile of VIOXX.

220. Defendants' effort to avoid the results of the VIGOR Study by falsely claiming naproxen was cardio-protective led to a stern formal reprimand from the FDA. Thus, the Second Warning Letter, dated September 17, 2001, which was addressed to defendant Gilmartin, admonished Merck for:

- engaging in a "promotional campaign [that] discounts the fact that in the VIGOR Study, patients on VIOXX were observed to have a four to five fold increase in myocardial infarctions [heart attacks] compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (Naproxen)"; and

- "assert[ing] that VIOXX does not increase the risk of [heart attacks] and that the VIGOR finding is consistent with Naproxen's ability to block platelet aggregation like aspirin. ***That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that VIOXX may have pro-thrombotic properties***" (emphasis added).

221. The Second Warning Letter also stated:

> You have also engaged in ***promotional activities that minimize the VIOXX/ Coumadin (warfarin) drug interaction, omit important risk information, make unsubstantiated superiority claims against other NSAIDs***, and promote VIOXX for unapproved uses and an unapproved dosing regimen. In addition, ***in misrepresenting the VIOXX/warfarin drug interaction you also misrepresent VIOXX's safety profile*** by minimizing the potentially serious risk of significant bleeding that can result from using VIOXX and warfarin concomitantly.

* * *

Promotional Audio Conferences

We are aware of six promotional audio conferences, presented on behalf of Merck by Peter Holt, MD that are in violation of the Act and its implementing regulations. . . .

* * *

The promotional audio conferences . . . were false or misleading in that they minimized the MI results of the VIGOR Study, minimized the VIOXX/Coumadin drug interaction, omitted important risk information, made unsubstantiated superiority claims, and promoted VIOXX for unapproved uses and an unapproved dosing regimen.

* * *

Press Release

We have identified a Merck press release entitled, "Merck Confirms Favorable Cardiovascular Safety Profile of VIOXX," dated May 22, 2001, that is also false or misleading for similar reasons stated above. Additionally, ***your claim in the press release that VIOXX has a "favorable cardiovascular safety profile," is simply incomprehensible, given the rate of MI and serious cardio-***

vascular events compared to Naproxen. The implication that VIOXX's cardiovascular profile is superior to other NSAIDs is misleading; in fact, serious cardiovascular events were twice as frequent in the VIOXX treatment group (101 events, 2.5%) as in the Naproxen treatment group (46 events, 1.1%) in the VIGOR Study.

Oral Representations

Merck sales representatives have engaged in false or misleading promotional activities that also minimize the potentially serious MI results observed in the VIGOR trial. Specifically, Merck sales representatives made false or misleading statements to DDMAC reviewers at two different professional meetings. At your exhibit booth during the 119th Annual Meeting of the Maryland Pharmacists Association (MPhA), in Ocean City, Maryland, June 9 – June 12, 2001, your representative stated that the increased MI rate seen in patients on VIOXX in the VIGOR Study is due to the fact that Naproxen works just like aspirin (i.e., inhibits clotting and platelet aggregation). In addition, during the Annual Meeting of the American Society of Health Systems Pharmacists (ASHP), in Los Angeles, California, June 3 – June 6, 2001, your representatives stated that VIOXX had a greater MI rate in the VIGOR trial

> because Naproxen is cardioprotective, having platelet effects similar to aspirin. ***These statements made by your sales representative are misleading for the reasons stated above***. (Emphasis added.)

222. The Second Warning Letter "concluded that [Merck's promotional activities and marketing for VIOXX] [were] false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act [] and applicable regulations concerning adverse cardiovascular events."

223. Notwithstanding the Second Warning Letter, Defendants continued to misrepresent the safety of VIOXX. On September 24, 2001, a *Bloomberg News* report about the Second FDA Warning Letter quoted Merck representative Christine Fanelle: "***We continue to stand behind the overall safety and the cardiovascular safety of the product,*** but our immediate priority is to discuss our response" with the FDA (emphasis added).

224. Defendants' assurance concerning the purported safety, including the cardiovascular safety, of VIOXX was materially false and misleading because Defendants, since before the commercial introduction of the drug, had in their possession evidence that VIOXX posed significant cardiovascular risks to its users.

225. On October 18, 2001, Defendants issued a Company press release announcing Merck's financial results for the third quarter 2001, the period ending September 30, 2001. Defendant Gilmartin commented on the Company's performance, stating:

> Our five key growth drivers [ZOCOR, VIOXX, COZAAR/HYZAAR, FOSAMAX and SINGULAIR], which had increased sales of nearly 30% over the first nine months of 2000 and now account for two-thirds of Merck's worldwide human health sales, continue to lead Merck's income growth.

Defendants also stated:

> VIOXX, a once-a-day medicine, is the only COX-2 selective agent approved in the United States for both osteoarthritis and acute pain. Available in more than 70 countries, VIOXX is Merck's second largest-selling medicine. In the third quarter, VIOXX continued new prescription leadership within the coxib market in the United States and in many European and Latin American countries. VIOXX became the first and only coxib approved for acute pain in a European Union country when it launched with that indication in the United Kingdom in September. In the third quarter, VIOXX achieved $795 million in sales, an increase of 29% over the same quarter last year.

226. The October 18, 2001 press release was materially false and misleading because once Defendants chose to speak about the purported success and advantages of VIOXX they had a duty to speak fully and truthfully and to disclose the serious cardiovascular risks created by VIOXX, which jeopardized its commercial

viability and its ability to contribute substantial revenues over the life of Merck's patent.

227. In addition to concealing the cardiovascular risks associated with VIOXX, and engaging in a scheme to suppress, distort, and obscure the truth through a pattern of deception and intimidation, Defendants, beginning in late 2001, also misled investors by publicly characterizing all actions filed against Merck concerning VIOXX's adverse cardiovascular safety profile as being "***completely without merit***" (emphasis added). For example, in Merck's October 18, 2001 press release, Defendants stated:

> [F]our federal lawsuits and a number of state lawsuits, involving individual claims as well as purported class actions, have been filed against the company with respect to VIOXX. . . . The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. ***The company believes that these lawsuits are completely without merit*** and will vigorously defend them (emphasis added).

228. The October 18, 2001 press release was materially false and misleading because, in light of VIOXX's adverse safety profile, the lawsuits filed against the Company with respect to VIOXX were not "completely without merit." Defendants' misrepresentation was either repeated or incorporated by reference in at least the following documents Defendants filed with the SEC during the Class Period: Merck's 10-Qs for the fiscal quarters ended March 31, 2002, June 30, 2002, September 30, 2002, March 31, 2003, June 30, 2003, September 30, 2003, March 31, 2004, and June 30, 2004;

as well as the Company's 10-K's for the fiscal years ended December 31, 2001, December 31, 2002, and December 31, 2003.

229. Given the lawsuits concerning the cardiovascular risks, the number of which significantly increased throughout the Class Period, Defendants were not only motivated to misrepresent, conceal, distort, obscure, and downplay VIOXX's adverse safety profile to protect the revenue stream created by its "blockbuster" drug, but also to avoid potentially devastating legal costs and liability. Indeed, as a result of the VIOXX withdrawal, and Defendants' effective admission of the drug's cardiovascular risks, as alleged herein, it has now been estimated to the court hearing the multidistrict VIOXX Product Liability Litigation that Merck will ultimately face as many as "100,000 cases against it over the VIOXX painkiller."

230. On or about November 13, 2001, Defendants filed with the SEC Merck's Form 10-Q for the third quarter 2001. The Form 10-Q was signed by defendants Henriques and Frazier. The Form 10-Q repeated substantially the same materially false and misleading statements concerning VIOXX that were made in Merck's October 18, 2001 press release referred to above.

231. Also on November 13, 2001, *The Financial News*, in an article entitled "Analysis of Celebrex Safety Data Show No Increased Risk of Cardiovascular Adverse Events Compared to NSAIDs Studied," reported:

> An analysis of safety data, representing over 13,000 patients from the new drug application (NDA) and 8,000 patients in the

> Celecoxib Long-term Arthritis Safety Study (CLASS), supports that CELEBREX(R) (celecoxib capsules) is not associated with an increased risk of cardiovascular (CV) adverse events compared to the NSAIDs studied. These findings were presented this week at the scientific sessions at the 65th annual meeting of the American College of Rheumatology.

232. In response to news that Pfizer, Merck's competitor in the Cox-2 drug business, had purportedly demonstrated that Celebrex did not increase the risk of heart attack, Defendants continued to misrepresent the cardiovascular profile of VIOXX. On December 11, 2001, *Bloomberg News* reported that Defendants had announced that Merck was planning a study of heart risks associated with VIOXX. According to the *Bloomberg News* article, defendant Scolnick explained that Merck will conduct more research on VIOXX so it can be "100 percent sure" of VIOXX's safety. Although, as detailed herein, Defendants had concealed and misrepresented clinical study results showing that VIOXX caused serious cardiovascular incidents, defendant Scolnick falsely assured the market: "Whatever the answer is in these studies, we will report it to the world." In fact, since Merck's only possible response to the Celebrex study was to protect its VIOXX franchise and to continue to misrepresent, conceal, distort and obscure the true serious cardiovascular risks of the drug by countering with the claim that it would conduct a study of its own, the announcement of a study to the "100 percent sure" of VIOXX was part and parcel of Defendants' scheme and artifice to mislead the public

into believing that there were no adverse cardiovascular risks relating to the use of VIOXX.

233. Nevertheless, Defendants' statements reported in the December 11, 2001 *Bloomberg* article were still materially false and misleading because they failed to disclose and misrepresented that, as Defendants already were aware, VIOXX created a greater risk of heart attack, and therefore they could not be "100 percent sure" of VIOXX's safety. Rather, announcing the proposed study was a gambit intended to convince the public that Merck had no fear that a new round of clinical studies would disclose that VIOXX showed an increased level of cardiovascular risks. Given Defendants' history of manufacturing both the protocols used for such studies and the result, Defendants' announcement of a new study was nothing more than a public relations ploy intended to blunt any criticism of VIOXX.

234. On January 22, 2002, Defendants issued a Company press release announcing Merck's financial results for the full year 2001. Defendant Gilmartin commented on the Company's performance:

> Our five key growth drivers, which also are our five largest products, now account for 68% of Merck's worldwide human health sales and continue to lead Merck's income growth. These medicines are true breakthroughs — they offer novel approaches to disease treatment, help large, underserved patient populations and are effective, well-tolerated and convenient. ***The market-growth potential for these medicines remains strong*** (emphasis added).

Defendant Merck stated:

> VIOXX was the product leader in 2001 within the coxib class for new prescription volume growth in the United States. Pain relief and gastrointestinal safety continue to be the primary needs in the arthritis and pain market. In December, VIOXX was approved for relief of acute pain and pain from dysmenorrheal in 13 member states of the European Union and in Norway and Iceland. For the year, VIOXX achieved $2.6 billion in sales, an increase of 18% with $550 million in the fourth quarter.

235. The January 22, 2002 press release was materially false and misleading because it failed to disclose the increased risk of heart attack attributable to VIOXX, which jeopardized its "marked-growth potential." Once Defendants chose to speak about the purported safety, success, and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks attributable to VIOXX, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

236. On March 15, 2002, Defendants were forced to withdraw the original NDA for ARCOXIA, thereby putting further pressure on Defendants to conceal the adverse cardiovascular profile of its blockbuster drug VIOXX. As result, Merck's dependence on VIOXX for its future revenues significantly increased.

237. Moreover, due to Merck's dependence on VIOXX for its financial future, and its consequent need

to suppress, obscure, and distort the truth regarding the serious risks posed by VIOXX, which Defendants knew would devastate Merck's business, as well as increased scrutiny of Merck's VIOXX testing procedures and presentation of those results caused by the discovery in the VIOXX personal injury cases, its competitors, and the medical profession in general, in March 2002, Defendants secretly halted the clinical study it previously announced to blunt criticism of VIOXX's health risks, which defendant Scolnick stated would have provided "100 percent" assurance of VIOXX's safety. *The New York Times,* in an article entitled "Merck Canceled an Early Study of VIOXX," which was published after the Class Period (on February 8, 2005), reported that "previously undisclosed company documents show that the drug maker was poised to begin a major cardiovascular study of [VIOXX] in 2002, and abruptly dropped the project before it was set to start."

238. *The New York Times* reported:

> [M]erck has never disclosed how extensively it planned that study, which was known inside the company as the Valor trial, or how close it came to starting it. ***By early 2002, the drug maker had already contacted outside researchers to oversee the test, had approached a competing drug maker to obtain anti-ulcer drugs to ease the possibility of side effects, and had prepared a 70-page protocol that spelled out how the test was to be conducted, according to documents reviewed by The New York Times.***

> One planning document, for example, shows that the first patients were supposed to enter the study in June 2002 and the last patient was to leave it in January 2004. But in mid-March 2002, just days before company researchers had planned to submit the study's protocol to the F.D.A., top executives of the drug maker ordered work on the project halted. It was never revived.
>
> "I have the unpleasant task of having to inform you that the VIOXX CV Outcomes Study has been placed on hold," a memo dated March 13, 2002, and sent to dozens of Merck employees worldwide, stated. "***At this time we do not have any of the details that led to this decision, however, we have been informed that upper management is in the process of reviewing the various study options.***"
>
> * * *
>
> Asked to provide a copy of a document from March 2002 which summarized the decisions given at the time for not going forward with the study, [a Merck spokeswoman] said that no such document existed (emphasis added).

239. The timing of Defendants' decision to call off the Valor Study is also significant. *The New York Times* reported:

> ***Work on the Valor trial was halted at the same time that officials from Merck and the F.D.A. were concluding lengthy and heated negotiations over how Vioxx's label would reflect data from an earlier trial, known as the Vigor study, which indicated that the widely used painkiller posed potential cardiovascular risks*** (emphasis added).

240. As detailed herein, the VIOXX labels were themselves materially false and misleading because, among other things, they failed to disclose properly that the use of VIOXX significantly increased the risk of heart attack or other serious cardiovascular event. Moreover, the fact that Merck had "negotiations" with the FDA over the disclosures in the VIOXX label leaflet was not disclosed until after the Class Period. Thus, the public remained unaware, throughout the Class Period, that the FDA had sought more stringent and greater disclosures by Merck regarding the use of the drug.

241. On March 21, 2002, Defendants filed with the SEC Merck's Form 10-K for 2001. The Form 10-K, which was signed by Defendants Gilmartin, Lewent, Scolnick, and Henriques, stated:

> The unit volume growth from sales of Merck human healthy products was driven by five key products: Zocor, Vioxx, Cozaar/Hyzaar, Fosamax and Singulair. Also contributing to Merck's human health volume growth were Proscar, Maxalt and Cancidas, which was launched in 2001.

* * *

> Vioxx, Merck's second largest-selling product, continued its strong growth in 2001 and was the product leader within the COX-2 class for new prescription volume growth in the United States. It exceeded the $2 billion sales mark faster than any other product in Merck's history. Pain relief and gastrointestinal safety continue to be the primary needs in the arthritis and pain market. Vioxx is now available in 68 markets around the world as a once-a-day treatment for osteoarthritis, acute pain and dysmenorrheal and, in some countries outside the Untied [sic] States, rheumatoid arthritis. Physicians are responding favorably to the Company's pain studies in which Vioxx 50 mg was compared to acetaminophen in combination with either codeine 60 mg or oxycodone 5 mg, which are commonly prescribed narcotics. In addition, an initiative with U.S. hospital resulted in a favorable formulary status for Vioxx at more than 3, 000 major hospitals. In November 2001, Vioxx was approved for symptomatic relief in the treatment of adult rheumatoid arthritis in all EU member states through the mutual recognition procedure. In December 2001, Vioxx, under the trade names Ceoxx or Vioxx Acute, was also approved for relief of acute pain and pain from dysmenorrheal in 13 member states of the EU.

242. The Form 10-K was materially false and misleading in that once Defendants chose to speak about

the purported safety, success, advantages, and expanded uses of VIOXX they had a duty to speak fully and truthfully, and to disclose information concerning the serious cardiovascular risks of VIOXX, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

243. On April 3, 2002, Defendants issued Merck's 2001 Annual Report, which included a letter to shareholders, signed by defendant Gilmartin, which stated:

> Dear Shareholder: ***All the vital information about how your Company faired in 2001 is in this report.*** However, when you see this "more" icon that's an indication there's additional information you may find of interest on the web. You can access that information in the accompanying URL or by turning to www.anrpt.20001.com (emphasis added).

Needless to say, the referenced website failed and omitted to disclose the true health risks of VIOXX or Defendants' knowledge thereof. Defendant Gilmartin's letter to shareholders in the Company's 2001 Annual Report also stated:

> ***Our five key drivers of growth*** — Zocor, ***Vioxx***, Cozaar/Hyzaar, Fosamax and Singulair — now represent more than two-thirds of our worldwide pharmaceutical sales. ***In addition, they have significant remaining growth potential based on key studies***. . . (emphasis added).

244. The 2001 Annual Report, and defendant Gilmartin's letter to shareholders, were materially false and misleading in that, contrary to Defendants' representation, shareholders did not have access to "vital information" concerning the Company's performance, including information on the adverse safety profile of VIOXX, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent. In addition, as "key studies" (including Study 090, VIGOR, and ADVANTAGe) demonstrated that VIOXX posed serious cardiovascular risks, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent, Defendants' representation that VIOXX had "significant remaining growth potential based on key studies" was false.

245. On April 11, 2002, Defendants issued a Merck press release announcing that the FDA had "approved changes to the prescribing information for VIOXX . . . to include results from the landmark 8,000 patient [VIGOR] Study." Defendants also stated that "[t]he prescribing information also has been revised to include cardiovascular data from VIGOR." Defendants, however, went on to falsely assure investors again that VIOXX was safe, quoting defendant Scolnick as stating that: "***Merck is confident in the . . . safety profile of VIOXX***" (emphasis added).

246. The April 11, 2002 press release was materially false and misleading in light of the serious cardiovascular risks posed by VIOXX, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

247. According to a memorandum (the "Congressional Memorandum") issued after the Class

Period (on May 5, 2005) by the minority members of the United States House of Representatives Government Reform Committee (the "House Government Reform Committee"), there was a two-year delay between the time that Merck filed a request (on June 29, 2000) to change the initial VIOXX label to reflect the purported beneficial GI findings in the VIGOR Study and the time that the initial VIOXX label was changed to "include cardiovascular data from VIGOR":

> The extended delay resulted, in part, from FDA's need to convene an advisory committee meeting and conduct extra analyses. ***It also was due to a series of disputes between the agency and the company. Under the Food, Drug and Cosmetic Act, FDA and manufacturers must agree on label changes. For approximately six months, Merck resisted a variety of FDA's proposals, leading to an extended series of conference calls to negotiate differences. Throughout this period, Merck continued to use the Cardiovascular Card with physicians*** (emphasis added).

248. The Congressional Memorandum reports that the "FDA initially requested that the label warn physicians that VIOXX could cause heart attacks and other cardiovascular problems." To that end, the FDA proposed the VIOXX Label include the following information in the "Warning" section:

> ***Vioxx should be used with caution in patients at risk of developing cardiovascular thrombotic events such***

> ***as those with a history of myocardial infarction and angina and in patients with pre-existent hypertension and congestive heart failure.***
>
> ***The risk of developing myocardial infarction in the VIGOR study was five fold higher in patients treated with Vioxx 50 mg (0.5%) as compared to patients treated with naproxen (0.1%)***....This finding was consistent in a smaller and shorter study using Vioxx 25 mg that allowed the use of low dose ASA [aspirin.] Prospective, well powered, long-term studies required to compare the incidence of serious CV events in patients taking Vioxx versus NSAID comparators other than naproxen have not been performed (emphasis added).

249. According to the Congressional Memorandum, the FDA's proposed warning "***was unacceptable to Merck.***" (Emphasis added.) In fact, although Defendants knew that there was a "causal relationship" between the use of VIOXX and the significant cardiovascular risks (which is more than required by FDA regulations concerning information that must be set forth as a "Warning"), Defendants, apparently recognizing that such a warning would have a material impact on VIOXX sales, failed to include the FDA's proposed "Warning," ***in form or substance***, in ***any*** of the VIOXX labels during the Class Period.

250. The Congressional Memorandum provides further details concerning Defendants' failure to inform

physicians and patients, as well as the market, about VIOXX's adverse cardiovascular profile:

> On February 12, 2002, FDA proposed to Merck that the label include a special graphic called a Kaplan-Meier curve to show a worsening of cardiovascular risks on Vioxx for those with the longest exposure to the drug. During a teleconference, FDA officials stated that the "best way to display the data is the Kaplan Meier curve." FDA's minutes of the call add, "Note: ***The time devoted to how to best display cardiovascular safety from VIGOR reflects how important the Agency considers the topic of clear labeling of safety information.***" ***Merck objected to the idea*** (emphasis added).

251. As the Congressional Memorandum reveals, although the Second VIOXX Label (the label in use from about April 12, 2002 through about August 14, 2003) contained language concerning the "cardiovascular effects" of VIOXX, the language failed to adequately disclose the significant cardiovascular risks attributable to VIOXX. In addition to the general boilerplate language contained in the First VIOXX Label, the Second VIOXX Label stated:

> The information below should be taken into consideration and caution should be exercised when VIOXX is used in patients with a medical history of ischemic heart disease:

In VIGOR, a study in 8076 patients (mean age 58; VIOXX n=4047, naproxen n=4029) with a median duration of exposure of 9 months, the risk of developing a serious cardiovascular thrombotic event was significantly higher in patients treated with VIOXX 50 mg once daily (n=45) as compared to patients treated with naproxen 500 mg twice daily (n=19). In VIGOR, mortality due to cardiovascular thrombotic events (7 vs 6, VIOXX vs naproxen, respectively) was similar between the treatment groups. (See CLINICAL STUDIES, Special Studies, VIGOR, Other Safety Findings: Cardiovascular Safety.) In a placebo-controlled database derived form 2 studies with a total of 2142 elderly patients (mean age 75; VIOXX n-1067, placebo n=1075) with a median duration of exposure of approximately 14 months, the number of patients with serious cardiovascular thrombotic events was 21 vs 35 for patients treated with VIOXX 25 mg once daily versus placebo, respectively. In these same 2 placebo-controlled studies, mortality due to cardiovascular thrombotic events was 8 vs 3 for VIOXX versus placebo, respectively. The significance of the cardiovascular findings from these 3 studies (VIGOR and 2 placebo-controlled studies) ***is unknown***. Prospective studies specifically designed to compare the incidence of serious CV events in patients taking VIOXX versus NSAID comparators

or placebo have not been performed (emphasis added).

252. This language was materially false and misleading because, among other things:

(a) It failed to disclose that the use of VIOXX significantly increased the risk of heart attack or other serious cardiovascular event;

(b) VIOXX significantly increased the risk of heart attacks not only in individuals with a pre-existing cardiovascular condition, ***but also in all others***;

(c) Notwithstanding that VIOXX significantly increased the risk of heart attack for all patients, and that there was more than ***reasonable evidence*** of the cardiovascular risks attributable to VIOXX, Defendants failed to disclose any information concerning those risks in the "Contraindication" or "Warnings" sections of the Second VIOXX Label;

(d) Defendants included this language in the "Precaution's Section" of the label, which merely requires disclosure of "information regarding any special care to be exercised by the practitioner for safe and effective use of the drug" (21 C.F.R. § 201.57(3)(v)(f)), and therefore wrongfully minimized the serious cardiovascular risks attributable to VIOXX;

(e) The VIGOR Study findings were due to VIOXX's adverse cardiovascular safety profile — not to the purported cardio-protective characteristics of naproxen rationale represented by Defendants; and

(f) As the Congressional Memorandum states: "perhaps most important to Merck, the label included the statement that 'the significance of the cardiovascular findings of these three studies (VIGOR and 2 placebo-

controlled studies) is ***unknown***'" (emphasis added). Indeed, Defendants were more than aware of the "significance" of the VIGOR Study's findings, *i.e.*, the drug significantly increased the risk of heart attack or other cardiovascular event, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

253. With respect to the February 2001 meeting of the FDA Arthritis Advisory Committee, the Congressional Memorandum provides the following information:

> [T]he Committee voted that doctors be informed about the results of the VIGOR study, the trend toward excess heart attacks in osteoarthritis patients. ***Merck ignored this suggestion and instead instructed its sales representative to specifically not discuss the results with physicians and to reassure physicians by use of the Card.***
>
> The FDA addressed whether VIOXX's pre-approval studies, which formed the basis for the information contained in the Card, could be used to represent VIOXX's cardiovascular safety and informed the Committee that the studies should not be used in this way. The ***FDA told the Committee that to pool data from so many different incomparable studies was "fundamentally flawed"*** (emphasis added).

254. Additional information provided to Plaintiffs' counsel by former Merck VIOXX sales representatives provides further details on Defendants' scheme to conceal VIOXX's cardiovascular risks, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent:

(a) Although FME-2 was aware of the results of the VIGOR Study, Defendants, who train representatives "harder than anyone else in the industry," directed Merck's sales representatives to assure customers VIOXX did not cause heart attacks. Similarly, according to FME-3, FME-4, and FME-5, representatives were trained to downplay and minimize the cardiovascular findings from the VIGOR Study. According to FME-6, sales representatives were told repeatedly that the Company "***stands behind the safety profile***" (emphasis added) of VIOXX.

(b) According to FME-4, it was known throughout the Company that VIOXX was shown to cause more heart attacks. Yet, sales representatives were uniformly instructed to inform physicians who raised the VIGOR Study findings that Study participants given VIOXX were not permitted to take aspirin, which would have reduced their susceptibility to having a heart attack. (In fact, aspirin, a traditional NSAID, would counter any potential GI benefit of VIOXX.)

(c) According to FME-6, sales representatives were trained how to deal with the Second FDA Warning Letter, which, as reported in *The Wall Street Journal* November 1, 2004 article, was referred to within Merck as "obstacle handling." According to FME-6, Merck instructed its sales representatives to address the issue by stating that "patients in the VIGOR Study who were given VIOXX were arthritis patients who were

chronically on steroids and had a much higher risk for cardiovascular disease."

255. The Second VIOXX Label's inadequate disclosures were further minimized, distorted, and obscured by the intensity and credibility of Defendants' numerous public misrepresentations before and after issuance of the Second Warning Letter "confirming VIOXX's cardiovascular safety profile." For instance, as alleged herein, Defendants, by continuing to train the VIOXX sales representatives to misrepresent VIOXX's cardiovascular profile, were also able to rebut and counterbalance any questions concerning the drug's safety profile. The Congressional Memorandum states:

> ***After the label change, Merck altered its instructions to field representatives regarding cardiovascular risks. The new instructions still prohibited representatives from initiating discussions on any new cardiovascular data. But the instructions now drew heavily from the language in the label that emphasized uncertainty about the cardiovascular risk of the drug*** (emphasis added).

In addition, as alleged herein, through a pattern of deception and intimidation, Defendants also quelled the voices of those who, but for Defendants' wrongful conduct, may have raised questions concerning VIOXX's "cardiovascular effect."

256. On April 18, 2002, Defendants issued a Merck press release announcing financial results for the first quarter 2002, the period ending March 31, 2002.

Defendant Gilmartin commented on the Company's performance:

> With the continued growth of our five key franchises — ZOCOR, VIOXX, COZAAR/HYZAAR, FOSAMAX and SINGULAIR — along with our plans to file or launch 11 new medicines by 2006, we expect the core pharmaceutical business to deliver double-digit earnings per share growth in 2003 and ***top-tier performance over the longer term*** (emphasis added).

Defendants also stated:

> ***Vioxx, the Company's second-largest-selling medicine, continues to gain acceptance among physicians and patients worldwide. Global sales for the quarter were $650 million***. Last week, Merck announced that the FDA has approved changes to the prescribing information for VIOXX, under the gastrointestinal (GI) warning section, to include results from the landmark VIOXX Gastrointestinal Outcomes Research (VIGOR) study. The FDA also approved VIOXX 25 mg for the relief of the signs of rheumatoid arthritis in adults. VIOXX is now the first and only medicine that selectively inhibits the COX-2 enzyme that is proven to reduce the risk of developing clinically important gastrointestinal (GI) side effects in patients with or without risk factors for such GI side effects compared to the non-steroidal anti-inflammatory

> drug (NSAID) naproxen. In this study, the number of patients with serious cardiovascular thrombotic events in the group treated with VIOXX 50 mg (n=45) was higher than in the group taking naproxen (n=19). In a placebo-controlled database derived from two other studies (n=2.142), the number of patients with serious cardiovascular thrombotic events among those receiving VIOXX 25 mg was 21 compared to 35 for patients taking placebo. In these same two-placebo controlled studies, mortality due to cardiovascular thrombotic events was 8 versus 3 for VIOXX versus placebo, respectively. These data also are reflected in the prescribing information. The significance of the cardiovascular findings from these three studies (VIGOR and the placebo-controlled studies) ***is unknown*** (emphasis added).

257. The April 18, 2002 press release was materially false and misleading because, among other things: (i) Defendants were fully aware of the "significance of the cardiovascular findings," *i.e.*, that VIOXX posed significant cardiovascular risks, and (ii) once Defendants chose to speak about the purported advantages, success, and expansion of the use of VIOXX, they had a duty to speak fully and truthfully and to disclose VIOXX's adverse safety profile, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent. Indeed, Defendants' statements regarding the delivery of "top-tier [earnings]

performance over the long term" failed and omitted to disclose that any significant earnings to be produced by VIOXX were dependent on Defendants' ability to continue to misrepresent, conceal, distort, and obscure the truth regarding the safety risks of the drug. Furthermore, Defendants' statement that VIOXX "continues to gain acceptance among physicians and patients worldwide" was also materially false and misleading in light of Defendants' efforts, which proved to be successful, to train Merck's sales representatives to misrepresent, minimize, and conceal the true significant cardiovascular safety risks of VIOXX.

258. Also on April 18, 2002, subsequent to the release of the financial results for the first quarter of 2002, Merck held a conference call for analysts, money and portfolio managers, institutional investors, and large Merck shareholders. During the call, Mark Stejbach, the Merck spokesperson, commented on the "new labeling changes" to VIOXX, which purportedly included the results from the VIGOR Study:

> ***[I]mportantly there was a change to the precautions, again not the warnings, but the precautions*** regarding cardiovascular language and two effects there, there were the results of the vigor study that had been disclosed for some time that you all know about. And that showed a lower cardiovascular event rate for naproxen vs. VIOXX in the VIGOR Study. And importantly, also in the label now are the results of the safety results of two large placebo control studies in a large elderly population. And in that study we saw essentially no difference between VIOXX

> and placebo on the rate of cardiovascular. ***In fact, numerically VIOXX is even a little lower. But this is very reassuring and we think its part of the body of evidence that supports our belief that the effect seen in VIGOR were the results of the anti-platelet effect of naproxen***. Of course, VIOXX does not have an effect on platelets consistent with its selective inhibition and that's reflected in the label. And so appropriate patients should be given anti-platelet therapy. ***So, I think that's a position Merck has always had and now its quite clearly laid out in the labeling*** (emphasis added).

259. Defendants' statements during the conference call were materially false and misleading because (i) Defendants were fully aware of the "significance of the cardiovascular findings," *i.e.*, that VIOXX posed significant cardiovascular risks, and (ii) once Defendants chose to speak about the purported success of VIOXX, they had a duty to speak fully and truthfully and to disclose VIOXX's adverse safety profile, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent. Furthermore, Defendants' statement that VIOXX "continues to gain acceptance among physicians and patients worldwide," was also materially false and misleading in light of Defendants' efforts, which proved to be successful, to train Merck's sales representatives to misrepresent the significant cardiovascular safety risks of VIOXX. Further, Defendants once again attempted to discredit the VIGOR Study and to falsely attribute its results to

the non-existent cardio-protective attributes of naproxen and to portray VIOXX as cardio-neutral (and, indeed, as having lower cardiovascular risks than a placebo), rather than properly and truthfully disclose that VIOXX causes an increased risk of serious cardiovascular events.

260. On April 26, 2002, the Director Defendants, to continue the MSIP, filed the Registration Statement with the SEC, through which the Company registered an offering of 6,000,000 shares of stock. The Registration Statement was signed by the Director Defendants. The Registration Statement incorporated by reference Merck's Form 10-K for 2001, dated March 21, 2002, which was materially false and misleading as for the reasons set forth above, *i.e.*, once Defendants chose to speak about the purported safety, success, and advantages of VIOXX they had a duty to speak fully and truthfully, and to disclose information concerning the serious cardiovascular risks of VIOXX, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

261. On April 30, 2002, Defendants filed a Prospectus for the MSIP Offering, which incorporated by reference Merck's Form 10-K for 2001. Accordingly, the April 30, 2002 Prospectus was materially false and misleading for the reasons set forth above

262. On May 13, 2002, Defendants filed with the SEC Merck's Form 10-Q for the first quarter 2002, the period ending March 31, 2002. The Form 10-Q was signed by defendants Frazier and Henriques, and contained substantially the same materially false and misleading statements concerning the purported success and safety of VIOXX that were made in the Company's April 18, 2002 press release, referred to above.

263. On July 19, 2002, Defendants issued a Company press release announcing Merck's financial results for the second quarter 2002, the period ending June 30, 2002. Defendant Gilmartin was quoted as follows:

> ***Merck is pleased with the performance of our five key growth drivers [which includes VIOXX] and believe that bolstered with new data from clinical outcome trials, these medicines continue to have significant growth potential*** (emphasis added).

Defendants also stated:

> Global sales of VIOXX, the company's second-largest selling medicine, were $845 million this quarter. In April, the FDA approved changes to the approved changes to the prescribing information to include results from the landmark [] (VIGOR) Study and new indication with VIOXX 25 mg for the relief of signs and symptoms of rheumatoid arthritis in adults. ***VIOXX now is the only COX-2 specific inhibitor with a label demonstrating the proven risk reduction in clinically important gastrointestinal events compared to the non-steroidal anti-inflammatory drug (NSAID) naproxen and the only COX-2 specific inhibitor to offer once-daily 24-hour relief for osteoarthritis, rheumatoid arthritis and acute pain*** (emphasis added).

264. The July 19, 2002 press release was materially false and misleading because, among other things, once Defendants chose to speak about the purported success and advantages of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent. Furthermore, as Defendants were fully aware of the cardiovascular risks attributable to VIOXX, defendant Gilmartin's statement that VIOXX had "significant growth potential" was an outright lie. In addition, as alleged more fully below, Defendants' representations concerning VIOXX's label were also materially false and misleading.

265. Defendants' efforts to silence VIOXX critics knew no geographic bounds. For example, in the Summer of 2002, Dr. Joan-Ramon Laporte, editor of the journal for the Catalan Institute of Pharmacology in Barcelona, Spain, published criticisms of Merck's handling of VIOXX. After the criticisms were published, Merck officials sent Dr. Laporte a "rectification" for publication, which Dr. Laporte declined to publish. Merck thereafter sued Dr. Laporte and the Catalan Institute in Spain, demanding a public correction of inaccurate published information. Two years of litigation later, in January 2004, the Spanish court ruled that Dr. Laporte's publication accurately reflected the debate over VIOXX's safety, and ordered Merck to pay court costs. The Spanish Court's findings notwithstanding, Merck's litigation strategy helped to secure it two additional years of VIOXX sales. During this time period, Defendants made no effort to disclose the truth about VIOXX's adverse safety profile and instead continued to falsely assure the public VIOXX was safe.

266. Even while pursing litigation, Merck also sought to discredit Dr. Laporte personally and professionally. Dr. Laporte was a speaker at a Merck-sponsored annual pharmaceutical meeting for 1,000 Spanish family physicians in each of the preceding four years. After Dr. Laporte criticized VIOXX, Merck told the meeting's organizer that it would prefer if Dr. Laporte did not speak at the program, even though he had been a featured speaker at previous meetings. After the meeting organizer rejected the request to remove Dr. Laporte, Merck withdrew its financing of approximately $140,000 from the meeting. Dr. Ramon Morerai Castell, the meeting organizer, said that Merck's message in withdrawing its funding was clear — the Company would not tolerate any criticism of VIOXX.

267. On or about August 13, 2002, Defendants filed with the SEC Merck's Form 10-Q for the second quarter 2002. The Form 10-Q was signed by defendants Frazier and Henriques, and contained all of the materially false and misleading statements concerning VIOXX that were made in the Company's July 19, 2002 press releases, referred to above.

268. On October 18, 2002, Defendants issued a Company press release announcing Merck's financial results for the third quarter 2002, the period ending September 30, 2002. Defendants commented on the Company's performance:

> ***Merck's five key growth drivers*** — ZOCOR, ***VIOXX***, COZAAR and HYXAAR(a) and SINGULAIR — collectively had increased sales of 8% for the quarter and drove Merck's human health sales performance (emphasis added).

Defendant Gilmartin also commented:

> ***The potential of our five largest medicines continues to be demonstrated by results of key clinical outcome studies. By focusing on what we do best — discovering and developing important new medicines that improve and save people's lives — Merck's growth potential remains strong*** (emphasis added).

269. The October 18, 2002 press release was materially false and misleading in that, among other things, the "results of key clinical outcomes studies" demonstrated the serious cardiovascular risks attributable to VIOXX, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent, *i.e.*, the clinical studies demonstrated VIOXX's lack of "potential." As Defendants knew, only by falsely assuring the market that VIOXX was safe would "Merck's growth potential remain strong." Furthermore, the October 18, 2002 press release was materially false and misleading because once Defendants chose to speak about the purported success of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent. Further, Defendants' statement that "What [Defendants] do best" is to "improve and save people's lives" failed and omitted to disclose that VIOXX, perhaps the Company's most important drug, took people's lives.

270. During Defendants' third quarter 2002 conference call, Defendants sought to "dodge" questions concerning their progress in studying the documented cardiovascular effects associated with VIOXX. A participant on the call queried: "[Defendant] Ed Scolnick last December had basically told us there would be a Vioxx cardiovascular safety study performed, what's the status of beginning that trial or have those plans been abandoned?" In response, the Merck spokesperson stated:

> In terms of the cardiovascular outcome studies, you're right that we discussed doing those studies and we have not abandoned them, in fact, we're continuing to make progress on those, it's a very complex area as you all know and we're researching this area .... [S]o we'll continue with some of these ongoing things, continue to update the scientific community, but I know... we are still planning cardiovascular outcome studies for Vioxx and look forward to, hopefully soon, be able to discuss that in more detail and in a comprehensive manner across the products. Okay, so with that I apologize, we've run over....

271. Defendants' statements during the conference call were materially false and misleading in that they concealed the significant safety risks affecting VIOXX that were known to Defendants through, among other things, numerous clinical studies, as detailed above.

272. On or about November 13, 2002, Defendants filed with the SEC Merck's Form 10-Q for the third quarter 2002. The Form 10-Q was signed by defendants Frazier and Henriques, and contained the same materially false and misleading statements concerning VIOXX that were made in the Company's October 18, 2002 press release, referred to above. In addition, the Form 10-Q contained certifications, signed by defendants Gilmartin and Lewent, as required pursuant to §302 of the Sarbanes-Oxley Act of 2002, which represented, among other things: "Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

273. On January 28, 2003, Defendants issued a Company press release announcing Merck's financial results for the fourth quarter and full year 2002, the periods ending December 31, 2002. Defendant Gilmartin was quoted as follows:

> New data released in October with respect to VIOXX underscores the proven gastrointestinal (GI) safety profile of VIOXX. An analysis combining data from 20 trials of more than 17,000 arthritis patients presented at the American College of Rheumatology meeting showed that VIOXX significantly reduced by 62 percent the incidence of confirmed upper-GI perorations, ulcers and bleeds compared to four widely used non-selective, non-steroidal anti inflammatory

> drugs (NSAIDs). The analysis is consistent with the significant reduction of clinically important GI events vs. naproxen seen in the landmark 8,000 patient . . . (VIGOR) study.

274. The January 28, 2003 press release was materially false and misleading because once Defendants chose to speak about the purported safety, success, and advantages of VIOXX and the "landmark" VIGOR Study, they had a duty to speak fully and truthfully about the serious cardiovascular risks attributable to VIOXX, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

275. On or about March 21, 2003, Defendants filed with the SEC Merck's Form 10-K for 2002. The Form 10-K was signed by, among others, defendants Gilmartin, Lewent, and Henriques. The Form 10-K contained certifications, signed by defendants Gilmartin and Lewent, as required pursuant to §302 of the Sarbanes-Oxley Act of 2002, which represented, among other things: "Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report." The Form 10-K contained the same materially false and misleading statements concerning VIOXX that were made in Merck's January 28, 2003 press release, referred to above.

276. On March 24, 2003, Defendants issued Merck's 2002 Annual Report, which included defendant Gilmartin's letter to shareholders, which stated:

> ***[W]e conduct our business with the highest standards of ethics and integrity. And finally, we develop strong, principled leaders who focus not only on results, but on how those results are achieved*** (emphasis added).

277. In the Annual Report, Defendants also stated:

> Vioxx, Merck's once-a-day coxib, remains the largest and most prescribed arthritis pain medication across many markets worldwide, including Europe, Canada and Latin America. For this year, Vioxx sales grew 8% over 2001, achieving $2.5 billion in sales in 2003, worldwide sales of VIOXX and Arcoxia, are expected to be approximately $2.6 billion to $2.8 billion.

278. Defendants' comments to shareholders in the 2002 Annual Report were false and misleading because, among other things, although Defendants were aware, through clinical trials and other means, of VIOXX's adverse safety profile, which endangered — and indeed, was taking — lives, as well as the commercial viability of the drug and its ability to generate substantial revenues over the life of Merck's patent, they failed to disclose the drug's adverse cardiovascular safety profile to the market, *i.e.*, Defendants were more concerned about "results," than about "how such results were achieved." In addition, Defendants' comments in the 2002 Annual

Report were materially false and misleading because once Defendants chose to speak about the purported success and future sales of VIOXX, they had a duty to speak fully and truthfully about the serious cardiovascular risks attributable to the drug, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

279. Furthermore, as Defendants were engaging in a scheme to conceal VIOXX's cardiovascular risks since as early as 1996, Defendants' statements in the 2002 Annual Report concerning their "ethics" and "integrity" were outright false. Further evidencing the falsity of Defendants' representations, on November 14, 2004 *The New York Times* reported:

> In 2001, Dr. Deepak L. Bhatt, a cardiologist at the Cleveland Clinic, proposed to Merck a study of Vioxx in patients with severe chest pain. Merck declined, saying the patients proposed for the study did not reflect typical Vioxx users. In Dr. Bhatt's view, the company feared what it might find if it directly examined the dangers of Vioxx, one of Merck's biggest products, with sales last year of $2.5 billion.
>
> "They should have done a trial like this," Dr. Bhatt said. "If they internally thought this drug was safe in patients with heart disease, there was no reason not to do it."

280. On April 21, 2003, Defendants issued a Merck press release announcing financial results for the first quarter 2003, the period ending March 31, 2003.

The press release stated with regard to the Company's performance:

> ZOCOR, FOSAMAX, COZAAR and HYZAAR, SINGULAR, and VIOXX collectively had increased sales of 19% for the first quarter of 2003, compared to the first quarter of 2002, and drove Merck's pharmaceutical sales performance.
>
> Merck's once-a-day coxib, VIOXX, has been launched in 77 countries worldwide. In the United States, VIOXX is the most widely prescribed and frequently preferred coxib on managed care formularies. VIOXX is the leading coxib outside the United States. Global sales for the quarter were $527 million.

281. The April 21, 2003 press release was materially false and misleading in that, among other things, once Defendant chose to speak about the purported success of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

282. On or about May 14, 2003, Defendants filed with the SEC Merck's Form 10-Q for the first quarter 2003. The Form 10-Q was signed by defendants Frazier and Henriques, and repeated the same materially false and misleading statements contained in the April 21, 2003 press release, referred to above. In addition, the Form 10-Q contained certifications, signed by defendants Gilmartin and Lewent, as required pursuant

to §302 of the Sarbanes-Oxley Act of 2002, which represented, among other things: "Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

283. On July 21, 2003, Defendants issued a Merck press release announcing financial results for the second quarter 2003, the period ending June 30, 2003, which stated:

> ***Merck continues to focus on maximizing the growth of its key products while broadening its portfolio of breakthrough medicines.*** Sales ZOCAR, FOSAMAX, COZAAR and HYZAAR, SINGULAR, and VIOXX collectively increased 7% for the second quarter of 2003, compared to the second quarter of 2002, and drove Merck's pharmaceutical sales performance, representing 64% of total pharmaceutical sales (emphasis added).
>
> Data presented at the 55th Annual Scientific Meeting of the American Academy of Neurology in April profiled research results for VIOXX in the treatment of acute migraine headaches. VIOXX 25 mg once daily and 50 mg once daily relieved acute migraine pain within two hours and reduced certain symptoms associated with migraine headaches of moderate to severe intensity. VIOXX was

well tolerated compared to placebo in this 557-patient study.

284. The July 21, 2003 press release was materially false and misleading in that, among other things, once Defendants chose to speak about the purported success of VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning VIOXX's adverse cardiovascular profile, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

285. On or about August 15, 2003, Defendants issued a new VIOXX label (the "Third VIOXX Label") to include a brief description of an aspirin endoscopy study, and the maximum recommended dose for patients with moderate hepatic impairment which did not in any way address VIOXX's adverse cardiovascular profile. Indeed, notwithstanding that, by the time Defendants issued the Third VIOXX Label in August 2003, they had known about VIOXX's adverse cardiovascular safety profile for as many as six years, it failed to make proper disclosure of, and instead misrepresented and wrongfully minimized, the serious cardiovascular risks attributable to VIOXX. Indeed, the Third VIOXX label contained essentially the same materially false and misleading statements concerning VIOXX's cardiovascular safety profile as were made in the Second VIOXX label.

286. In addition, as alleged herein, by: (i) falsely confirming the cardiovascular safety profile of VIOXX throughout the Class Period; (ii) training Merck sales representatives to materially misrepresent the cardiovascular risks attributable to VIOXX; and (iii) engaging in a scheme to conceal, mischaracterize, and

obscure the truth about the safety risks of VIOXX through a pattern of deception and intimidation, Defendants suppressed, distorted and counterbalanced any purported information concerning the "cardiovascular effect" of the drug.

287. On or about August 13, 2003, Defendants filed with the SEC Merck's Form 10-Q for the second quarter 2003. The Form 10-Q repeated the same materially false and misleading statements contained in the July 21, 2003 press release referred to above. The 10 Q was signed by defendants Frazier and Henriques. In addition, the Form 10-Q contained certifications, signed by defendants Gilmartin and Lewent, as required pursuant to §302 of the Sarbanes-Oxley Act of 2002, which represented, among other things: "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

288. On October 22, 2003, Defendants issued a Merck press release announcing financial results for the third quarter 2003, the period ending September 30, 2003, which stated:

> Merck anticipates reported earnings per share from continuing operations for 2003 of $2.90 to $2.95 as a result of workforce reductions, implementation of the new distribution program for U.S. wholesalers, and product sales trends for its major in-line products. In the aggregate, the major in-line products have not met the company's challenging revenue targets

> that it believed were achievable. Overall, they are growing and competing well in their respective categories.

Defendants also stated:

> Global sales of Merck's first once-a-day coxib, VIOXX, were $510 million during the third quarter and $1.8 billion for the first nine months. In the United States, VIOXX remains the most-widely prescribed and frequently preferred coxib on managed care formularies. More than 85 million prescriptions have been written in the United States since VIOXX was first introduced in 1999.

289. Later that day, minutes before the market closed, *Reuters News Service* published an article entitled "Merck to Cut 4,400 Jobs, posts Flat Earnings." The article revealed that sales of VIOXX were declining due to data "suggesting it might slightly raise the risk of heart attacks, and the growing perception that VIOXX did not have any greater efficacy than traditional NSAIDS":

> Merck & Co. Inc. said on Wednesday it would cut 4,400 jobs and reported disappointing earnings, hurt by falling sales of arthritis medicine VIOXX and a paucity of profitable new drugs. . . . Sales of VIOXX fell 32 percent in the period to $510 million. The arthritis drug is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks, and the growing perception that

> its pain-fighting capabilities are no better than traditional painkillers.

As Defendants were well aware, VIOXX posed more than a "slight" risk of heart attack and the clinical data available to Defendants — some of which, unbeknownst to the public, Defendants had in their possession even before VIOXX was commercially introduced — did not merely "suggest[ ]" VIOXX "might slightly raise the risk of heart attacks," but that it posed serious cardiovascular risks, which jeopardized VIOXX's commercial viability and its ability to generate substantial revenues over the life of Merck's patent. Nevertheless, in the face of the *Reuters* story, Defendants acted to immediately and vociferously discredit any report that raised the possibility of VIOXX causing an increased risk of heart attack in order to allay any concerns with respect to the safety profile of the drug. Defendants' wrongdoing caused the price of Merck stock to remain artificially high.

290. On October 30, 2003, *The Wall Street Journal* published an article, entitled "VIOXX Study Sees Heart-Attack Risk," which revealed that a Merck-funded study at Harvard University-affiliated Brigham and Women's Hospital in Boston (the "Brigham Study") found an increased risk of heart attack in patients taking VIOXX, compared with patients taking Pfizer's drug Celebrex, and compared with patients not taking any painkiller. The article stated:

> Brigham & Women's Hospital rheumatologist and epidemiologist Daniel H. Solomon headed the study, which looked at records of 54,475 Medicare patients, all of them over 65.

> Researchers found that the apparent cardiac risk was greatest in the first 90 days in which a patient is taking VIOXX, which generically is known as rofecoxib. ***In the first 30 days, the researchers found, VIOXX was linked to a 39% increased heart-attack risk compared with Celebrex. Between 30 and 90 days, that increased relative risk was 37%.***
>
> * * *
>
> ***Eric J. Topol, chairman of cardiovascular medicine at the Cleveland Clinic and one of the authors who first raised the issue two years ago, called the research "the best study to date."***
>
> * * *
>
> ***The new study, Dr. Topol said, "greatly substantiates our concerns about the cardiac side effects."*** He observed that the possible cardiac effects of VIOXX appear "worse with the higher doses" (emphasis added).

291. On November 2, 2003, in the face of the October 30, 2003 *The Wall Street Journal* article, defendant Reicin, Executive Director of Clinical Research for Merck, publicly denounced the study and announced: "In our placebo-controlled randomized trials, we have found no significant difference between VIOXX and placebo." Defendant Reicin also stated:

"'Randomized clinical trials are the 'gold standard,' and this isn't such a trial."

292. Defendant Reicin's statements on behalf of Merck were materially false and misleading in that they failed to disclose and misrepresented the truth concerning the safety of VIOXX, and that, even when the cardiovascular risks associated with VIOXX were revealed in randomized clinical trials, such as Study 090, VIGOR, and ADVANTAGe, Defendants either concealed, misrepresented, discredited, or rejected those findings.

293. In a letter to the editor of *The Wall Street Journal*, bearing the heading "Merck Stands Behind The Safety of VIOXX," which was published on November 5, 2003, defendant Kim, President of Merck Research Laboratories, stated:

> ***Nothing is more important to Merck than the safety of its medicines. Your Oct. 30 story about an observational analysis of Vioxx was incomplete***. The article discussed only the findings from this analysis where Vioxx appeared to have an unfavorable risk profile, but failed to report other findings from the same analysis that showed no statistically significant difference in the risk of heart attack for Vioxx compared with other commonly used anti-inflammatory drugs.
>
> ***The story also failed to report that another observational analysis presented at the same scientific meeting also showed no statistically significant difference in heart attacks between***

Vioxx and two widely used anti-inflammatory drugs, ibuprofen and diclofenac. A complete reporting of the data presented might have remedied the mistaken impression left by the story.

Observational methods lack the rigor of randomized, controlled clinical trials, and have led the scientific community astray before. For example, decades of observational analyses suggested that hormone replacement therapy reduced heart disease risk in post-menopausal women, but the landmark Women's Health Initiative, a randomized, controlled trial, found the opposite with an estrogen progestin combination. That is why observational studies must be interpreted with caution. Merck stands behind the safety of Vioxx based on the results of numerous randomized, controlled clinical trials.

Finally, it should be noted that Merck has previously announced it is conducting large prospective, randomized placebo-controlled clinical trials that, when added to the extensive data from clinical trials already available, will provide an even more comprehensive picture of the cardiovascular safety profile of Vioxx (emphasis added).

294. Defendant Kim's statements were materially false and misleading because they misrepresented and

failed to disclose the truth concerning the safety of VIOXX, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

295. Not only did Defendants publicly disparage and attempt to discredit the results of the Brigham Study, and therefore continue to mislead the market concerning the cardiovascular risks of the drug, but according to a *Wall Street Journal* article, entitled "Merck Takes Author's Name Off VIOXX Study," which was published later on in the Class Period (May 18, 2004), Merck had ordered the name of one of its epidemiologists removed from the list of authors of the Brigham Study in an effort to distance itself from the Study's adverse findings concerning VIOXX's safety profile:

> Stepping into thorny ethical territory, drug titan Merck & Co. ordered the name of one of its epidemiologists purged from the list of authors on a research paper — after the study produced an unflattering portrait of a blockbuster drug Merck happens to make.
>
> And a look at successive published versions of the paper, which link the painkiller Vioxx to an increased risk of heart attack, shows that the effort failed to fully cover its tracks. At one point, the epidemiologist's full name was deleted from the top of the article, but her last name was accidentally left in an errant footnote. It vanished completely from the final version, published earlier this month

in the prestigious American Heart Association journal Circulation.

* * *

"It's an enormous disservice to the reader," says Drummond Rennie, deputy editor of the Journal of the American Medical Association. "If the people up there in the list of authors aren't responsible for everything in the article, something's wrong. ***It's completely unethical.***"

* * *

"Merck disagreed with the conclusions and didn't think it was appropriate to have a Merck author," company spokeswoman Mary Elizabeth Blake said.

The eighth [author] was Carolyn C. Cannuscio, a Merck epidemiologist.

When the article appeared, its conclusion — that Vioxx "was associated with an elevated relative risk of acute myocardial infarction [heart attack]" — was the same as before. So was the methodology. But this time, Dr. Cannuscio's name was missing.

* * *

Harvard, which submitted the final version of the article for publication,

says it omitted Dr. Cannuscio's name on orders from Merck. "It was definitely not our decision that she be removed as an author," says Harvard medical professor Jerry Avorn, a co-author. "Our team worked closely with Dr. Cannuscio from the design of the project through the collection and interpretation of the data, and the writing of the paper. She played an active role in all those areas."

* * *

Whatever the case, several of Dr. Cannuscio's co-authors say she should get credit for her year-and-a-half's work on the Vioxx research. Asked if Dr. Cannuscio agreed with the decision to remove her name, Dr. Santanello said, "It was Merck's decision."

For Merck, maintaining Vioxx sales is essential. With $2.55 billion in 2003 sales, it is among Merck's top drugs. The company is under considerable pressure these days, with some promising experimental drugs having failed and the cholesterol drug Zocor facing patent expiration in 2006.

* * *

JAMA editor Catherine DeAngelis is disappointed that Merck didn't see this as a chance to show that sponsors of research can willingly publish findings that run

> contrary to their own interests. ***"They missed a wonderful opportunity to get some good publicity for the pharmaceutical industry," she says. "Aren't they seeking truth?"*** (Emphasis added).

In reality, Defendants were well aware of the truth concerning the safety of VIOXX, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent. To ensure sales of VIOXX remained strong, however, Defendants continued to suppress, obscure, and distort the truth about VIOXX. In an article that appeared in the *Archives of Internal Medicine* after the Class Period (January 2005), Daniel Solomon and Jerry Avorn, the authors of the Brigham Study, commented on Merck's scheme to conceal the truth about VIOXX: ***"[E]ven after funding and agreeing with the design of the Study, Merck publicly discredited our findings."*** (Emphasis added.)

296. On or about November 13, 2003, Defendants filed with the SEC Merck's Form 10-Q for the third quarter 2003, the period ending September 30, 2003, which, among other things, repeated the materially false and misleading statements that the VIOXX personal injury and third party payor lawsuits "were without merit." In fact, Defendants were well aware of the severe cardiovascular risks associated with VIOXX, but to protect Merck, the VIOXX franchise, and the value of their own shares, Defendants falsely denied the connection between VIOXX and the injuries sustained by the plaintiffs in the personal injury cases.

297. The 10-Q was signed by defendants Frazier and Henriques. In addition, the Form 10-Q contained certifications, signed by defendants Gilmartin and Lewent, as required pursuant to §302 of the Sarbanes-Oxley Act of 2002, which represented, among other things: "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

298. On January 27, 2004, Defendants issued a Company press release announcing Merck's financial results for the fourth quarter 2003 and full year 2003, the periods ending December 31, 2003, which stated:

> Global sales of VIOXX, Merck's first once-a-day coxib, reached $731 million for the fourth quarter and $2.5 billion for the year. Full-year 2003 sales represented a 2% increase over 2002. U.S. mail-order-adjusted prescription levels for VIOXX decreased by 5% during the quarter. In the aggregate, estimated wholesaler buy-in for VIOXX had a favorable impact of $40 million on revenues for the quarter.
>
> VIOXX continues as the most-widely available coxib on managed care formularies in the United States. VIOXX is the only coxib in the United States that offers 24-hour pain relief in a once-daily tablet for all indications, with more than 91 million prescriptions written in the United States since its introduction in 1999.

> Outside the Untied States, VIOXX is the best-selling arthritis and pain medicine. Supplemental NDAs are under review with the FDA for additional indications for migraine and juvenile rheumatoid arthritis. If approved, these uses are expected to enhance the efficacy profile of this product.

299. The January 27, 2004 press release was materially false and misleading in that, among other things, once Defendant chose to speak about VIOXX, they had a duty to speak fully and truthfully and to disclose information concerning the serious cardiovascular risks. In addition, Defendants' representations concerning "supplemental NDAs" were deceptive as they ignored that the commercial viability of VIOXX and its ability to generate substantial revenues over the life of Merck's patent were, in fact, in jeopardy. Indeed, rather than concede the serious cardiovascular risks of VIOXX, Defendants continued to represent that the drug's use could be expanded to be used for, among others, children.

300. Beginning in March 2004, Defendants modified Merck's national television and print the advertisements. As alleged above, prior to March 2004, those advertisements made no mention of any cardiovascular issues associated with VIOXX. The new 2004 advertisements stated that, if a patient has "a history of heart problems," that patient should consult with their doctor before taking VIOXX. This recommendation, however, was meaningless since VIOXX was a prescription drug and could not legally be purchased without a consultation with a doctor. The advertisements, even with the "consult you doctor"

modification were materially false and misleading because: (i) they failed to disclose that the use of VIOXX significantly increased the risk of having a heart attack or other serious cardiovascular event; and (ii) VIOXX significantly increased the risk of heart attack for not only for individuals "who had a heart condition," but also for individuals who were entirely healthy. Moreover, as detailed herein, Defendants had actively misled the medical community, and the public, about VIOXX's safety.

301. On or about March 10, 2004, Defendants filed with the SEC Merck's Form 10-K for 2003, which was signed by, among others, defendants Gilmartin, Lewent, and Henriques. The Form 10-K repeated the false and misleading statements made in the January 27, 2004 press release, as set forth above. In addition, the Form 10-K contained certifications, signed by defendants Gilmartin and Lewent, as required pursuant to §302 of the Sarbanes-Oxley Act of 2002, which represented, among other things: "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

302. Also on March 10, 2004, *Bloomberg News* reported that a study funded by Pfizer, which examined possible risks posed by various painkillers, found that VIOXX was linked to a higher risk of heart attack for patients with high blood pressure. Continuing Defendants' effort to negate, minimize, and discredit any link between VIOXX and increased cardiovascular risk, according to the *Bloomberg News* report, Merck spokeswoman Mary-Elizabeth Blake stated that "the

company disagrees with the findings" and that "the study wasn't designed well." *Bloomberg* also reported that Blake stated: "Merck is carrying out large trials of VIOXX that will help pinpoint its safety."

303. Defendants' March 10, 2004 assurance regarding the safety of VIOXX and effort to disparage the findings of the Pfizer study were materially false and misleading because, as Defendants were well aware, VIOXX caused an increase in adverse cardiovascular events. Similarly, Defendants' statements that Merck was conducting "large trials of VIOXX that will help pinpoint its safety" were also materially false and misleading in that, among other things, Defendants already were aware of VIOXX's adverse safety profile.

304. On or about April 6, 2004, Defendants issued a new VIOXX label (the "Fourth VIOXX Label") to reflect that VIOXX had been approved for the acute treatment of migraine in adults. Notwithstanding that, by the time Defendants issued the Fourth VIOXX Label in April 2004, they had known about VIOXX's adverse cardiovascular safety profile, and engaged in a scheme to suppress the truth, for as many as seven years, the Fourth VIOXX Label contained essentially the same materially false and misleading statements concerning VIOXX's safety profile as were made in the Second and Third VIOXX Labels.

305. In addition to the false and misleading statements alleged above, the Fourth VIOXX Label included an addendum, entitled "*Patient Information about VIOXX*." Although Defendants were aware of VIOXX's adverse cardiovascular safety profile, *i.e.*, that it significantly increased the risk of heart attack and cardiovascular events for *healthy individuals*, as well as for those with pre-existing heart conditions, the

Addendum was also materially false and misleading as it included a section on "*Who should not take VIOXX*," but failed to disclose that, as made clear by the withdrawal of VIOXX a little more than 5 months after the Addendum was issued, *none of these individuals should take VIOXX*, *i.e.*, the commercial viability of the drug was, virtually, non-existent.

306. The Addendum included Defendants' first acknowledgment that "Heart attacks and other serious cardiovascular events" may be a "possible side effect[] of VIOXX." Nevertheless, Defendants continued their effort to distort, negate, minimize, and obscure the truth regarding the safety risks of VIOXX by stating in the Addendum that "[s]erious ***but rare*** and potential life-threatening side effects have been reported in patients taking VIOXX." (Emphasis added.) Defendants' statements were materially false and misleading because, as defendant Scolnick recognized, the cardiovascular risks "were mechanism based as we worried it was." Moreover, the Addendum failed to disclose: (i) the magnitude of the cardiovascular risks attributable to VIOXX, which, by this time, may have resulted in, according to Dr. Graham of the FDA, as many as 139,000 heart attacks, 30% to 40% of which may have resulted in death; and (ii) that, dating as far back as 1996, Defendants knew of these risks and engaged in a willful scheme to suppress, conceal, distort, and obscure the truth.

307. In addition, the aforementioned materially false and misleading statements were, at the very least, counterbalanced by Defendants: (i) publicly confirming the cardiovascular safety profile of VIOXX throughout the Class Period, including defendant Kim doing so on August 26, 2004, *i.e.*, five months after the Addendum

was issued, and just over a month before Defendants withdrew VIOXX; (ii) training Merck sales representatives to materially misrepresent the cardiovascular risks attributable to VIOXX; and (iii) engaging in a scheme to suppress the truth through a pattern of deception and intimidation.

308. Furthermore, the aforementioned representations concerning "possible side effects" were themselves downplayed by the introductory statement set forth in the Addendum:

> This leaflet does not take the place of talking with your doctor about your condition or treatment (emphasis added).

As Defendants were aware, Merck sales representatives had been trained to conceal VIOXX's adverse cardiovascular safety profile. As such, Defendants' statement, which minimized the effect of any purported disclosure, was itself materially false and misleading.

309. On April 22, 2004, Defendants issued a Company press release announcing Merck's financial results for the first quarter 2004, the period ending March 31, 2004. In the press release, Defendants announced: "Merck's largest products, which continue to benefit from ongoing clinical studies and new treatment options, drove the company's sales." Defendants also announced: "Worldwide sales of VIOXX, Merck's arthritis and pain medicine, reached $661 million for the first quarter of 2004. U.S. mail-order-adjusted prescription levels for VIOXX decreased by 3% during the quarter. In markets outside of the United States, VIOXX continues to be the best-selling arthritis and pain medicine."

310. The April 22, 2004 press release was materially false and misleading in that, among other things, once Defendants chose to speak about the purported success of VIOXX, they had a duty to speak fully and truthfully, and to disclose the serious cardiovascular risks created by VIOXX, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

311. On or about May 7, 2004, Defendants filed with the SEC Merck's Form 10-Q for the first quarter 2004. The Form 10-Q repeated the same materially false and misleading statements contained in the April 22, 2004 press release referred to above. The Form 10-Q was signed by defendants Frazier and Henriques. In addition, the Form 10-Q contained certifications, signed by defendants Gilmartin and Lewent, as required pursuant to §302 of the Sarbanes-Oxley Act of 2002, which represented, among other things: "Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

312. On June 10, 2004, Defendants filed a Prospectus for the MSIP Offering (the "June 10, 2004 Prospectus"), which contained essentially the same materially false and misleading statements concerning "considerations" set forth in the Registration Statement. The June 10, 2004 Prospectus also incorporated by reference Merck's 2001 Form 10-K, and therefore was materially false and misleading for the reasons set forth above with respect to that SEC filing. The June 10, 2004

Prospectus also incorporated by reference Merck's 2003 Form 10-K and Form 10-Q for the period ended March 31, 2004, and therefore was also materially false and misleading for the reasons set forth above.

313. On July 21, 2004, Defendants issued a Company press release announcing Merck's financial results for the second quarter 2004, the period ending June 30, 2004. In addition to reporting worldwide VIOXX sales were $653 million for the second quarter and $1.3 billion for the first six months of 2004, Defendants again boasted about the "success" of VIOXX, noting that "[o]utside of the United States, VIOXX continues to be the best-selling arthritis and pain medicine."

314. The July 21, 2004 press release was materially false and misleading in that, among other things, once Defendant chose to speak about the purported success of VIOXX, they had a duty to speak fully and truthfully, and to disclose the serious cardiovascular risks created by VIOXX, which jeopardized its commercial viability and its ability to generate substantial revenues over the life of Merck's patent.

315. On or about August 6, 2004, Defendants filed with the SEC Merck's Form 10-Q for the second quarter 2004, the period ending June 30, 2004. The Form 10-Q repeated the same materially false and misleading statements contained in the July 21, 2004 press release referred to above. The Form 10-Q was signed by defendants Frazier and Henriques. In addition, the Form 10-Q contained certifications, signed by defendants Gilmartin and Lewent, as required pursuant to §302 of the Sarbanes-Oxley Act of 2002, which represented, among other things: "Based on my

knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

316. On August 25, 2004, *Bloomberg News* reported that a study, funded by the FDA involving almost 1.4 million Kaiser Permanente health care members (the "Kaiser Study"), found that "[t]he difference in heart risk was statistically significant between a recommended dose of VIOXX, 25 mg a day or less, and Celebrex." Specifically, the Kaiser Study, which was led by Dr. David Graham of the FDA, found that patients taking VIOXX had a 50% greater chance of heart attack and sudden cardiac death than patients taking Celebrex. The Kaiser Study also found that VIOXX, at a dose of 25 mg a day, more than tripled the risk of heart attack compared with patients who had not taken any painkiller within the past two months.

317. On August 26, 2004, Defendants, through the *Business Wire*, moved immediately to refute and discredit the Kaiser Study so as to allay any investor concerns by announcing:

> Merck strongly disagrees with the conclusions of an observational analysis by Graham et al, presented at an international medical meeting this week, which evaluated the rate of cardiovascular events in patients taking COX-2 specific inhibitors VIOXX (rofecoxib) and Celebrex (celecoxib) and in patients taking non-selective NSAIDs. This analysis is a retrospective database analysis — not a

clinical trial. Observational analyses have limitations, often conflict with each other, and must be interpreted within the context of data from large, randomized, controlled clinical trials.

It is important to note that, although the analysis was funded by the Food and Drug Administration (FDA) under contract with Kaiser Permanente, the conclusions presented by the authors do not necessarily reflect the views of the FDA (emphasis added).

318. In addition, defendant Kim stated:

This retrospective analysis is based only on a database review. Observational analyses do not have the rigor of randomized, controlled clinical trials. The robust clinical trial data available support the safety of VIOXX. ***Based on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of VIOXX.... Nothing is more important to Merck than the safety of our medicines*** (emphasis added).

319. On August 27, 2004, the *San Jose Mercury News* quoted Merck spokesperson Mary Elizabeth Blake, as stating: ***"We are certainly confident in the efficacy and safety of VIOXX"*** (emphasis added).

320. Defendants' continued assurances concerning the safety of VIOXX, even days before VIOXX was

pulled from the markets, including their immediate and vociferous rejection of the Kaiser Study findings, were materially false and misleading in light of the serious cardiovascular risks posed by the drug, which were known to Defendants.

Merck Announces A Worldwide Withdrawal Of Vioxx

321. On September 30, 2004, just over a month after Defendants publicly rejected the Kaiser Study findings, and reaffirmed the "safety, including cardiovascular safety" of VIOXX, the Company announced at a press conference and through a press release issued on the *Business Wire* that, "effective immediately," it was withdrawing VIOXX worldwide. Defendants stated that their "decision" was based on the recommendation of an independent External Safety Monitoring Board (the "ESMB"), which was overseeing a long-term study by Merck to evaluate the efficacy of VIOXX (25 mg) in preventing colorectal polyps (the "APPROVe Trial"). According to Defendants, the ESMB recommended that the APPROVe Trial be halted because of "an increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy."

322. That same day, Defendants also held a conference call for analysts to further discuss the withdrawal. Defendant Gilmartin stated:

> We are taking this action because we believe it serves the interests of patients ... ***We believe it would have been possible to continue to market VIOXX with labeling that would incorporate these new data. However, given the***

> ***availability of alternative therapies and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take*** (emphasis added).

323. Defendant Kim explained Merck's decision to "voluntarily" withdraw VIOXX:

> The APPROVe trial, although primarily focused on the efficacy of VIOXX in preventing colon polyps, also monitored the cardiovascular safety profile of the drug in the 2,600 patients involved. Importantly, this was a prospective, randomized, placebo-controlled, double-blind clinical trial. Approximately half of the patients were on VIOXX, while the other half were on placebo. The trial was scheduled to be completed later this year. This clinical trial was overseen by an external Steering Committee, comprised of leading medical experts in the field. In addition, an External Safety Monitoring Board closely monitored safety in the trial.
>
> Last Thursday evening, the chair of the Steering Committee informed us that an External Safety Monitoring Board had recommended that we stop the study because of emerging evidence of a cardiovascular risk.
>
> ***The study also found, however, that beginning after 18 months, there was a discernible and unexpected increased***

risk for confirmed cardiovascular events in patients taking VIOXX. While the reasons for these results are uncertain, ***the data do suggest a risk to patient safety, beginning after 18 months of continuous therapy.***

After receiving the data last Friday morning, we analyzed it thoroughly throughout the weekend. Beginning on Sunday evening, through Monday, we held meetings with numerous external medical experts, including members of the Steering Committee and the External Safety Monitoring Board. These experts provided diverse clinical perspectives on the data and on how Merck should proceed.

While acknowledging that many patients have benefited from VIOXX, we believe that the voluntary withdrawal that we are announcing today is in the best interest of patients. Accordingly, on Tuesday, we informed the members of our Board of Directors of the results, and of our decision to voluntarily withdraw VIOXX. Later that day, we met with the FDA and informed them of our plan. Subsequently, we began to inform other regulatory authorities around the world.

When we learned of these results last Thursday evening, we moved quickly to answer the question of what is in the

> ***best interest of patients. We believe our decision reflects Merck's commitment to patient safety*** (emphasis added).

324. Defendant Gilmartin concluded the call by issuing the following statement:

> [Defendant Lewent] pointed out we are also fortunate to have the financial strength to be able to make this decision. We would have made it regardless, but I want to emphasize we do have the financial strength to make this kind of decision.

325. In immediate response to Defendants' public revelation about the truth concerning VIOXX's adverse cardiovascular profile, and the drug's lack of commercial viability and inability to generate substantial revenues over the life of Merck's patent, the price of Merck securities plummeted. For instance, on September 30, Merck shares fell almost 27%, or more than $12 per share, to close at $33 per share. The decline was the greatest one-day percentage price decline of Merck stock since January 1990. The reported trading volume was 145,048,600 shares, more than 426% greater than the next highest reported trading volume since January 1990 (34,024,200 shares on November 21, 2003). The $0.50 to $0.60 decrease in earnings per share that Merck announced on September 30, 2004, represents the loss of at least $1.1 billion in annual earnings. The one-day decline wiped out a staggering ***$27 billion*** of the total market capitalization of the Company. Merck was by far the worst performing stock in the Dow Jones 30 Industrials Average, the S&P 500 Index, and the S&P Pharmaceuticals Index, each of which it is a member.

326. On the night of September 30, on the PBS *Nightly Business Report*, Defendants continued their wrongful scheme by falsely assuring the market that, prior to the APPROVe Study, they were unaware of the serious problems that ultimately forced them to "voluntarily" withdraw VIOXX from the market. Defendant Gilmartin falsely stated: "***It was totally unexpected***. But my instinctive reaction when Doctor Peter Kim called me to inform me of this was to say to him immediately, Peter, ***we're going to make this decision based on patient safety.***" (Emphasis added.)

327. On October 1, 2004, securities analysts and market professionals expressed shock at Merck's sudden about-face in light of Defendants' repeated public assurances, throughout the Class Period, concerning the safety of VIOXX:

(a) Cumins Catherwood, who helps manage $900 million at Walnut Assets Management in Philadelphia, commented: "***This is just like an avalanche coming out of nowhere.***" (Emphasis added.)

(b) A Morgan Stanley report stated: "Yesterday, MRK announced the ***surprise*** withdrawal of Vioxx." (Emphasis added.)

(c) A Cathy Financial report stated: "In a surprising move, Merck announced that it is voluntarily withdrawing its COX-II inhibitor VIOXX from worldwide markets. . . . ***This announcement came as a shock*** and is a major blow to Merck's already weak business fundamentals reflected by Zocor's expected patent expire in mid-2006 and its limited pipeline." (Emphasis added.)

(d) A Bear Stearns report stated: "***Stunningly***, Merck withdraws VIOXX from worldwide markets due

to new colorectal study which unexpectedly showed Vioxx has twice the cardiovascular risk versus placebo after 18 months of continuous use." (Emphasis added.)

(e) David Moskowitz, an analyst with Friedman, Billings & Ramirez noted: ***"This is nothing short of a disaster."*** (Emphasis added.)

(f) A Smith Barney Citigroup report stated: ***"MRK Suffers A Heart Attack***; Vioxx Withdrawn WorldWide." (Emphasis added.)

(g) An SG Cowen & Co. report noted: "[Merck's] liability risk could be $10B+."

328. Shocking as it might have been to the capital markets, Defendants' September 30, 2004 announcement only began the revelations of their long standing knowledge of the serious cardiovascular risks created by VIOXX, the drug's lack of commercial viability, and its inability to generate substantial revenues over the life of Merck's patent which proceeded the Class Period. In fact, Defendants continued to misrepresent and conceal the true extent of their knowledge concerning the serious problems with VIOXX, which as Defendants were well aware, jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent, and their efforts over many years to conceal those problems.

329. On October 6, 2004, *The Wall Street Journal* reported:

> A study led by a Food and Drug Administration safety official projects that the widespread use of Vioxx may have led to more than 27,000 heart attacks and sudden cardiac deaths before the drug's

abrupt withdrawal last week by Merck & Co. The number is in comparison to how many similar incidents would have occurred had the same patients been taking Celebrex, the Pfizer Inc. drug that competed with Merck's blockbuster arthritis treatment. (The analysis specifically found that from Vioxx's approval in 1999, through 2003, an estimated 27,785 heart attacks and sudden cardiac deaths "would have been avoided" had Celebrex been used instead of Vioxx.)

* * *

A Merck spokesman said in a statement that the company "cannot comment on the full study, as we have not yet had the opportunity to review it." He added that Merck believed that controlled clinical trials are "the best way to evaluate the safety of medicines," while "epidemiology studies are limited in their ability to understand effects" because researchers can't fully control for differences between different groups of patients.

* * *

The study found that people taking a high dose of Vioxx were 3.69 times as likely to have a serious cardiac event as people taking Celebrex, while the ratio for people taking a low dose of Vioxx was 1.5. It concluded that there was no evidence of a "substantial benefit with the high-dose

> strength" of Vioxx that would "counter-balance the level of cardiovascular risk" shown in various studies of the drug.

330. Defendants' statements, reported in *The Wall Street Journal*, were materially false and misleading as Defendants continued to conceal the fact that, as early as 1996, they were aware of the cardiovascular risks associated with VIOXX, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent, but had engaged in a successful campaign to suppress the truth.

331. Dr. Topol appeared on NBC's *Today Show* on October 7, 2004. In response to a question concerning why he believed that Merck had ignored or criticized studies that appeared during the Class Period indicating that VIOXX was unsafe, Dr. Topol replied: "Well, it's very obvious for — for Merck. They didn't want to go there. They didn't want to find out." In fact, based upon his studies of VIOXX, Dr. Topol believes that Merck "actively tried to promote the drug, knowing there was a cardiovascular risk ...."

332. As alleged herein, not until November 1, 2004 was the world alerted to Defendants' concerted efforts, dating as far back as ***1996***, to misrepresent and conceal the truth about the drug's safety profile, as well as its commercial viability and its ability to generate substantial revenues over the life of Merck's patent. That day, *The Wall Street Journal* published the highly detailed article, entitled "Warning Signs: E-mails Suggest Merck Knew Vioxx's Dangers at Early Stage," which revealed how Defendants, throughout the Class Period, had engaged in a willful scheme to suppress the

truth through, among other things, a pattern of deception and intimidation:

> When Merck & Co. pulled its big-selling painkiller Vioxx off the market in September, Chief Executive Raymond Gilmartin said the company was "really putting patient safety first." He said the study findings prompting the withdrawal, which tied Vioxx to heart-attack and stroke risk, were "unexpected." But internal Merck e-mails and marketing materials as well as interviews with outside scientists show that the company fought forcefully for years to keep safety concerns from destroying the drug's commercial prospects.
>
> Merck's first worry, in the mid-to-late 1990s, was that its drug would show greater heart risk than cheaper painkillers that were harsh on the stomach but were believed to reduce the risk of heart attacks. Several company officials discussed in e-mails how to design a study that would minimize the unflattering comparison, even while admitting to themselves that it would be difficult to conceal.

333. The November 1, 2004 *Wall Street Journal* article described in detail a number of internal Company e-mails and other documents that confirm Defendants' awareness of the seriousness of the safety issues affecting VIOXX from prior to the beginning of the Class Period. According to *The Wall Street Journal*:

A Nov. 21, 1996 memo by a Merck official shows the company wrestling with this issue. It wanted to conduct a trial to prove Vioxx was gentler on the stomach than older painkillers. But to show the difference most clearly, the Vioxx patients couldn't take any aspirin. In such a trial, "there is a substantial chance that significantly higher rates" of cardiovascular problems would be seen in the Vioxx group, the memo said.

A similar view was expressed in a February 25, 1997, e-mail by a Merck official, Briggs Morrison. He argued that unless patients in the Vioxx group also got aspirin, "you will get more thrombotic events" — that is, blood clots — "and kill [the] drug."

In response [to Morrison's email], Alise Reicin, now a Merck vice president for clinical research, said in an e-mail that the company was in a "no-win situation." Giving study subjects both Vioxx and aspirin, she wrote, could increase the "relative risk," apparently referring to gastrointestinal problems. But, she added, "The possibility of increased CV [cardiovascular] events is of great concern." From the context, it seems Dr. Reicin meant "increased" relative to older drugs.

She added in parenthesis: "I just can't wait to be the one to present those results to

senior management!" She proposed that that people with high risk of cardiovascular problems be kept out of the study so the difference in the rate of cardiovascular problems between the Vioxx patients and others "would not be evident."

In March 2000, the results of Vigor came in. They showed that Vioxx patients suffered fewer stomach problems than the Naproxen group, but significantly more blood-clot-related problems — precisely the sort of result anticipated in the 1996-97 internal documents. The heart-attack rate in the Vioxx group appeared to be four times as high as the naproxen group. (Later analysis would show it to be five times as high.)

The difference was so wide that Dr. Scolnick, the Merck research chief, appeared to recognize it couldn't come solely from Naproxen's protective effect but must involve some sort of risk inherent in Vioxx. In a March 9, 2000, e-mail with the subject line "Vigor," Dr. Scolnick said the results showed that the cardiovascular events "are clearly there." In an apparent acknowledgement that Vioxx's own mechanism was at least partially at fault for the heart data, he wrote: "it is a shame but it is a low incidence and it is mechanism based as we worried it was."

* * *

> A Merck internal marketing document reviewed by The Wall Street Journal, addressed to "all field personnel with responsibility for Vioxx," provided an "obstacle handling guide." If a doctor said he was worried that Vioxx might raise the risk of a heart attack, he was to be told that the drug "would not be expected to demonstrate reductions" in heart attacks or other cardiovascular problems and that it was "not a substitute for aspirin." This wasn't a direct answer.
>
> One training document is titled "Dodge Ball Vioxx" and consists of 16 pages. Each of the first 12 pages lists one "obstacle," apparently representing statements that might be made by a doctor. Among them are, "I am concerned about the cardiovascular effects of Vioxx" and "The competition has been in my office telling me that the incidence of heart attacks is greater with Vioxx than Celebrex." The final four pages each contain a single word in capital letters: "DODGE!"

334. According to the November 1, 2004 *Wall Street Journal* article, Defendants "also went on the offensive against academic researchers who began to question VIOXX's safety":

> (a) Gurkirpal Singh of Stanford University, . . . who was giving lectures sponsored by Merck and other companies, says he pressed Merck repeatedly for more cardiovascular safety data. When

Merck refused, Dr. Singh added a slide to his presentations that showed a man — representing the missing data — hiding under a blanket. "This was the first time they didn't answer my questions," he says. "With Vigor, suddenly it was a clampdown."

Merck cancelled several presentations by Dr. Singh that it had been scheduled to sponsor, and it didn't stop there. In October 2000, a Merck official, Louis Sherwood, called James Fries, a Stanford University Medical School professor, to complain that Dr. Singh's lectures were "irresponsibly anti-Merck and specifically anti-Vioxx," as Dr. Fries described the call in a January 2001 letter to Mr. Gilmartin, the Merck chief executive. The Merck official "suggested that if this continued, Dr. Singh would 'flame out' and there would be consequences for myself and for Stanford," Dr. Fries wrote.

Dr. Fries struck back. "There is a line that you can't go across. . . . It had to gone over that line," he said. He wrote to the Merck chief that researchers at several other top medical schools complained about "a consistent pattern of intimidation of investigators by Merck" on Vioxx.

Mr. Gilmartin responded that Merck had a "deep and abiding commitment to the highest ethical standards in all our dealings with physicians and other

healthcare providers." Dr. Fries and other researchers mentioned in the letter say the company did try to repair relations subsequently. Dr. Singh, an adjunct clinical professor at Stanford, says he stopped using the blanket slide after Merck gave him more data.

(b) Lee Simon, a rheumatologist at Beth Israel Deaconess Medical Center in Boston, says he publicly mentioned data showing Vioxx might be associated with a risk of high blood pressure and swelling. While Dr. Simon was closely involved with research on the rival Cox-2 drug Celebrex, he had worked with Merck in another area. Merck's Dr. Sherwood called Dr. Simon and one of his superiors at the hospital to complain that Dr. Simon's lectures were slanted against Vioxx. "I was shocked that there was a phone call made like that," Dr. Simon says. "The company was attempting to suppress a discussion about this data."

(c) M. Thomas Stillman, a professor at the University of Minnesota, also discussed the data on high blood pressure and swelling in his lectures — and also got a call from Dr. Sherwood. "We had a very direct conversation that I wouldn't call friendly," Dr. Stillman says. "It had a tone to me of, 'You better be careful of what you're saying.' ... I thought that was inappropriate." He had given Merck-

sponsored lectures but that ended after the disagreement, he says.

(d) In August 2001, researchers at the Cleveland Clinic published an analysis in the Journal of the American Medical Association [referred to above] that once again raised concerns about Vioxx's cardiovascular risks. Before it came out, Merck's Dr. Reicin and other officials met with the authors, arguing that "they didn't think there was a problem with the drug," says Steven Nissen, one of the Cleveland Clinic researchers. The company also asked the journal to run a Merck rebuttal but it refused, people with knowledge of the matter said at the time.

(e) One of Merck's most aggressive moves came against Joan-Ramon Laporte of the Catalan Institute of Pharmacology in Barcelona, Spain. In the summer of 2002, a publication of the institute edited by Dr. Laporte repeated criticisms of Merck's handling of Vioxx that had been published in the British journal Lancet. Soon after, Dr. Laporte says, Merck officials sent him a "rectification" to publish, but he responded that there would be no correction. After Merck officials approached him twice more, the company filed suit in a Spanish court against Dr. Laporte and the institute, taking advantage of a Spanish law that allows plaintiffs to demand a public correction of

> inaccurate published information In January of this year, a judge ruled that Dr. Laporte's publication accurately reflected the medical debate about the cardiovascular safety of Vioxx, and ordered Merck to pay court costs. This March, Dr. Laporte was a featured speaker at an annual update on the pharmaceutical world for about 1,000 Spanish family physicians. Merck had helped pay for the meeting for the previous eight years. It contacted the organizer, Ramon Morera i Castell, and told him that the company "preferred" if Dr. Laporte stayed off the program this year, says Dr. Morera. After Dr. Morera rejected the request, Merck withdrew its financing — about $140,000. Though there wasn't any specific threat, "the message was clear," says Dr. Morera.

335. In immediate response to *The Wall Street Journal* article, which revealed the truth concerning Defendants' wrongful conduct and their actual knowledge of the truth regarding VIOXX throughout the Class Period, which included their successful efforts to suppress, distort, and obscure the truth concerning VIOXX, and its commercial viability and ability to generate substantial revenues over the life of Merck's patent, Merck stock fell another $3.03, or about 9.7%, from the previous trading day's closing price to close at just $28.28 per share. The trading volume was 66,606,200 shares. Excluding September 30, 2004, the one-day percentage decline and the trading volume were the greatest since 1990. Between September 30, 2004 and November 1, 2004, Merck's market capitalization fell

by ***more than $37.2 billion***. On November 1, Merck was by far the worst performing stock in the Dow Jones 30 Industrials Average, the S&P 500 Index, and the S&P Pharmaceuticals Index, each of which it is a member.

336. On this same day, November 1, 2004, more negative press came out against Merck when *Fortune* magazine featured the VIOXX scandal as its cover story, "Will Merck Survive VIOXX?; Looming Lawsuits, Angry Investors, Declining Profits: The Vioxx Debacle Is Just The Latest Setback For The Proud Pharmaceutical Giant." In this article, defendant Gilmartin conceded that the withdrawal of VIOXX would hurt Merck's profits. The *Fortune* article also reported:

> In the time the drug was on the market, Merck spent more than $500 million on commercials trumpeting its virtues, according to the health-care industry research firm Verispan. By the time it was withdrawn, some 20 million Americans had taken it, and Vioxx was generating $ 2.5 billion in annual sales, making it the second-best-selling COX-2 inhibitor.

337. On November 1, 2004, securities analysts and market professionals voiced their surprise over Defendants' reported knowledge concerning the cardiovascular risks attributed to VIOXX, and their scheme to suppress the truth. For example, a Crowell, Weedon & Co. report stated: ***"[N]ew information indicates to us that the situation might not be as innocent as we thought.*** If WSJ findings [that appeared in the November 1, 2004 article] are true, shareholders uncertainties could linger in earnings, cash flow, and investor psychology for the foreseeable future.

. . . ***We recommend that investors sell Merck shares***" (emphasis added).

Post-Class Period Revelations Shed Further Light On Defendants Efforts To Suppress, Distort And Obscure The Truth

338. After the November 1, 2004 *Wall Street Journal* article revealed the truth concerning Defendants' efforts to suppress, distort, and obscure the truth concerning VIOXX's adverse cardiovascular safety profile, and the drug's commercial viability and ability to generate substantial revenues over the life of Merck's patent, additional public information was revealed, which shed further light on Defendants' wrongful conduct throughout the Class Period.

339. On November 5, 2004, *The Lancet* released a study (the "Lancet Study") that showed VIOXX should have been pulled from the market "***as early as 2000 because studies of the drug had clearly shown that it doubled the risk of heart attacks among users***" (emphasis added). ***Authors of the Lancet Study pooled data from 25,273 patients who had participated in 18 clinical trials conducted before 2001.*** That same day, *The Lancet* also published an editorial stating:

> Today we publish results from a cumulative meta-analysis which show that the unacceptable cardiovascular risks of Vioxx (rofecoxib) were evident as early as 2000 — a full 4 years before the drug was finally withdrawn from the market by its manufacturer, Merck.

* * *

The evidence showing that Vioxx caused significant adverse events was apparent well before data from the APPROVe trial triggered Merck's overdue intervention. This week's report by Peter Jüni and colleagues will add significant weight to ongoing litigation against Merck by patients who believe they were harmed by this drug.

These findings also come in the wake of new disclosures that suggest Merck was indeed fully aware of Vioxx's potential risks by 2000. ***Investigations by The Wall Street Journal have revealed e-mails that confirm Merck executives' knowledge of their drug's adverse cardiovascular profile — the risk was "clearly there", according to one senior researcher. Merck's marketing literature included a document intended for its sales representatives which discussed how to respond to questions about Vioxx — it was labelled "Dodge Ball Vioxx". Given this disturbing contradiction — Merck's own understanding of Vioxx's true risk profile and its attempt to gloss over these risks in their public statements at the time — it is hard to see how Merck's chief executive officer, Raymond Gilmartin, can retain the confidence of the public, his company's most important constituency***.

* * *

> The licensing of Vioxx and its continued use in the face of unambiguous evidence of harm have been public-health catastrophes. This controversy will not end with the drug's withdrawal. Merck's likely litigation bill is put at between US$10 and $15 billion. The company has seen its revenues and market capitalisation slashed. ***It has been financially disabled and its reputation lies in ruins***. It is not at all clear that Merck will survive this growing scandal (emphasis added).

340. Also on November 5, 2004, *CBSNews.com* issued an article, entitled "Merck Faces Slew of Vioxx Suits," which, among other things, quoted Stanford University medical professor Dr. James Fries, who had also been quoted in the November 1, 2004 *Wall Street Journal* article, which revealed that Defendants' fraudulent scheme dated as far back as 1996. In the *CBSNews.com* article, Dr. Fries elaborated on Defendants' wrongful scheme to suppress the truth concerning VIOXX's adverse cardiovascular safety profile during the Class Period: "I think Merck went over the line. ***Their approach was to try to get people fired for saying things they didn't agree with***" (emphasis added).

341. On November 8, 2004, Defendants filed with the SEC Merck's Form 10-Q for the third quarter 2004. The Form 10-Q disclosed that the United States Department of Justice had launched an inquiry into what Merck knew in advance of its withdrawal of VIOXX. According to Merck, the DOJ had served a subpoena on the Company "requesting information related to the Company's research, marketing and selling activities

with respect to VIOXX in a federal healthcare investigation ***under criminal statutes***." (Emphasis added.)

342. The Form 10-Q further revealed that the SEC also had begun an inquiry concerning VIOXX. Although Defendants did not specifically address the scope or purpose of the SEC inquiry, such investigations typically focus upon disclosure issues. The 10-Q explained:

> The Company cannot predict the outcome of these inquiries, however, it is possible that highly unfavorable outcomes, including a potential civil disposition from the SEC and/or potential civil or criminal dispositions from the Justice Department, could have a material adverse effect on the Company's financial position, liquidity and results of operations.

343. The November 14, 2004 broadcast of *60 Minutes*, which disclosed the results of Study 090, included an interview with a Merck sales representatives who, among other things, elaborated on how Defendants trained their sales force to lie to physicians about the cardiovascular risks associated with VIOXX. According to the sales representative, who "asked that [*60 Minutes*] not use her name and that [*60 Minutes*] alter her appearance and voice":

> We were supposed to tell the physician that Vioxx did not cause cardiovascular events. That, instead, in the studies Naproxen has aspirin like characteristics which made naproxen heart — a heart-

protecting type of drug, where Vioxx did not have that heart-protecting side.

* * *

I put my reputation on the line. I gave my physicians my word that Vioxx was a safe, effective product, and it's been pulled from the market because it was killing people (emphasis added).

344. On November 16, 2004, *Bloomberg News* reported that Standard & Poor's ("S&P") cut Merck's credit rating "three levels to AA- . . . cit[ing] reduced revenue and the elevated risk of litigation" stemming from the VIOXX recall. The *Bloomberg News* article quoted S&P as stating:

> At the very least, the litigation will be a major distraction for Merck's management and require significant legal expenditures, Standard & Poor's said in the statement. "The unpredictable legal process, as well as investigations regarding the propriety of company actions related to Vioxx, creates the potential for further deterioration of the company's credit risk profile in the foreseeable future."
>
> In making the cut, Standard & Poor's also cited concerns about a possible delay in approval of Merck's VIOXX successor, Arcoxia, and challenges revitalizing the company's pipeline.

The *Bloomberg News* article also reported that S&P's course of action had followed Moody's Investors Service similar action of lowering its credit rating for Merck debt.

345. On November 18, 2004, the United States Senate Finance Committee held hearings to investigate the circumstances surrounding the VIOXX withdrawal. Senator Charles Grassley, Chairman of the Committee, made the following remarks:

> On September 30th of this year, Merck withdrew Vioxx from the worldwide market. A blockbuster drug became a blockbuster disaster. Before September 30th, Vioxx was the subject of controversy in the scientific community behind closed doors.
>
> * * *
>
> Merck & Co. has a reputation for excellence in research and development. Yet today ***Merck is faced with one of the worst drug disasters in history. Merck acknowledged that Vioxx carried with it serious cardiovascular risks when it withdrew the drug from the market.*** During today's hearing we'll hear about the red flags that were raised about those risks in the years before and the years after Vioxx was approved by the FDA (emphasis added).

346. In testimony before the Committee, Dr. David Graham of the FDA stated that the APPROVe

Study, the Merck clinical study which precipitated VIOXX's withdrawal, showed that "high-dose VIOXX significantly increased the risk of heart attack and sudden death and that the high doses of the drug should not be prescribed or used by patients." Dr. Graham also testified that ***VIOXX has likely caused 88,000 to 139,000 heart attacks in the United States, with 30%-40% of those heart attacks resulting in fatality***. Dr. Graham further testified:

> A study report describing this work was put on the FDA website on Election Day. Among many things, this report estimated that nearly 28,000 excess cases of heart attack or sudden cardiac death were caused by VIOXX. ***I emphasize to the Committee that this is an extremely conservative estimate. FDA always claims that randomized clinical trials provide the best data. If you apply the risk-levels seen in the 2 Merck trials, VIGOR and APPROVe, you obtain a more realistic and likely range of estimates for the number of excess cases in the US. This estimate ranges from 88,000 to 139,000 Americans. Of these, 30%-40% probably died. For the survivors, their lives were changed forever***. It's important to note that this range does not depend at all on the data from our Kaiser-FDA study. Indeed, Dr. Eric Topol at the Cleveland Clinic recently estimated up to 160,000 cases of heart attacks and strokes due to VIOXX, in an article published in the New England

> Journal of Medicine. This article lays out clearly the public health significance of what we're talking about today (emphasis added).

347. Dr. Gurkirpal Singh, an Adjunct Clinical Professor of Medicine at Stanford University School of Medicine, provided the following testimony to the Senate Committee concerning the VIGOR Study:

> The VIGOR publication minimized the significance of heart attacks. While it prominently discussed the reduction of stomach bleeds in patients taking VIOXX, it did not mention that in spite of this, patients on VIOXX had more serious adverse events, and more hospitalizations than patients on Naproxen. The true rates for cardiovascular thrombotic adverse events (a prespecified study endpoint in the protocol), hypertension and congestive heart failure – which were all higher in the VIOXX group – were not shown in the paper at all.

Dr. Singh further testified that Merck's "failure to conduct large long-term safety studies subjected millions of patients over four years to a drug whose safety had been questioned by the FDA even before its approval."

348. The Company's post-Class Period actions belied Defendants' Class Period statements that "Merck puts patients first." On November 29, 2004, Merck filed a Form 8-K, which announced, among other things, that on November 23, 2004, five days after Dr. Graham testified before the Senate Finance Committee that VIOXX may have caused 139,000 heart attacks, Merck's

Management Committee adopted a plan to give the Company's top 230 managers (which includes the Individual Defendants, except for defendant Scolnick, who retired in 2002) the opportunity for a one time payment of up to three years of salary and bonus if another company bought Merck — or merely bought over 20 percent of its shares.

349. On November 30, 2004, *The New York Times*, in an article entitled "Merck Offering Top Executives Way Out," reported that "the plan . . . is the first formal acknowledgement that ***Merck is now so weakened that it may be vulnerable to takeover***" (emphasis added).

350. The *New York Times* also reported:

> [E]xperts on corporate governance said Merck's decision to adopt such a plan [or "golden parachute'] was particularly ill-timed. The board is rewarding executives for its problems with Vioxx and the company's inability to bring new drugs to the market, critics said. "It looks terrible, period," said Tom Dewey, a lawyer who has consulted for pharmaceutical companies and their boards.

The article quoted another corporate governance expert as stating:

> That provision creates the possibility that executives could receive a windfall by leaving even if Merck remained independent, said Nell Minow, editor of the Corporate Library, an independent research firm specializing in corporate

> governance. [Ms. Minow went on to say that Merck] "could have done it right. They chose not to do it right," [adding that] the better approach would have been to allow the payments only if a takeover was completed. Ms. Minow said that the severance plan was part of a broader pattern of weak oversight by Merck's directors. "***This is not a strong board. We rate board effectiveness, and we give them a poor grade***" (emphasis added).

351. On December 6, 2004, *The New York Times*, in an article entitled "With or Without Vioxx, Drug Ads Proliferate," reported on the likely impact of the inordinate amount of money that Merck spent on advertising VIOXX to the market:

> Critics complain that huge sums Merck spent to advertise VIOXX directly to consumers stimulated demand for the drug at the expense of cheaper — and perhaps safer — over-the-counter alternatives like ibuprofen.

In fact, in 2004, notwithstanding Defendants' knowledge concerning VIOXX's adverse cardiovascular profile, which jeopardized the drug's commercial viability and its ability to generate substantial revenues over the life of Merck's patent. Defendants spent more than $78 million on direct-to-consumer advertisement spending up until Defendants withdrew VIOXX in September of that year.

352. On December 7, 2004, *The Wall Street Journal*, in an article entitled "Celebrex Less Risky Than Vioxx," reported that results from a University of

Pennsylvania study indicated that "painkillers known as Cox-2 inhibitors ***don't all carry the same risk for heart attacks***." (Emphasis added.) *The Wall Street Journal* article also reported that the study, which was published in the December 6, 2004 online edition of *Annals of Internal Medicine*, found that:

> In the final analysis, the odds of a VIOXX user having a heart attack were 2.72 times higher than a Celebrex user, after adjustment for several factors, including body mass. That finding [] was statistically significant.

353. On December 8, 2004, Defendants issued a press release announcing Merck's financial results for the fourth quarter 2004, the period ending September 30, 2004. Among other things, the Form 10-Q commented on the impact of the VIOXX withdrawal on Company's performance:

> Merck anticipates fourth-quarter 2004 EPS of $0.48 to $0.53, which includes the impact of approximately $700 to $750 million in foregone sales of VIOXX and potential additional fourth-quarter costs for the withdrawal of VIOXX. As a result, Merck anticipates full-year 2004 EPS guidance of $2.59 to $2.64, which includes the expectation that the impact of the withdrawal will negatively affect full-year EPS by $0.50 to $0.55.

354. That same day, *The New York Times*, in an article entitled "Merck's Board Appoints Panel to Investigate Handling of Vioxx," reported that the

Company had commenced "an independent action into whether the company acted properly regarding Vioxx." The article also reported that "[t]he board [of directors] has appointed a seven-member special committee of outside directors to investigate Merck's actions and to respond to shareholder litigation." The article further reported that a "spokeswoman for Merck said she did not know whether the directors had opened the investigation at the request of federal prosecutors, who are also investigating Merck."

355. On December 19, 2004, *The New York Times*, in an article entitled "Medicine Fueled by Marketing Intensified Trouble for Pain Pills," reported on Defendants' motivation to conceal the cardiovascular risks attributed to VIOXX, *i.e.*, to increase sales:

> ***But having spent hundreds of millions of dollars to develop [the Drug,] the maker[] of . . . VIOXX, cheered on by Wall Street, had every motivation to expand their market[] beyond the older people most at risk of ulcers to encourage the [VIOXX's] use by millions more people of all ages. That was so even as, at least in the case of VIOXX, there was evidence as early as 2000 that a COX-2 drug could cause heart problems*** (emphasis added).

356. On December 21, 2004, *The Wall Street Journal*, in an article entitled "Management Missteps in '04 Hurt Companies, Endangered Customers," emphasized how Defendants "put customers at risk" by repudiating any reports that raised questions about the safety profile of Merck's "blockbuster drug" VIOXX:

> ***Merck's top executives put customers at risk for years – and badly damaged the company's reputation – by countering concerns raised by outside scientists about the potentially serious side effects of Vioxx, its big-selling painkiller. When CEO Raymond Gilmartin announced in September that Merck was pulling Vioxx off the market because of a study that tied the drug to heart-attack and stroke risks, he said that the findings were "unexpected" and that Merck was responding swiftly to the results. But internal Merck e-mails suggest that the company fought for more than four years to quash safety concerns raised by academics and other researches about the cardiovascular risks of Vioxx*** (emphasis added).

357. On January 20, 2005, the *CBS Market Watch*, in an article entitled "Study: Merck's VIOXX Was Overprescribed, Misused," reported that researchers at the University of Pennsylvania, who were authors of a study that would be published in the *Archives of Internal Medicine* January 2005 edition, stated that "VIOXX was prescribed mainly to patients who stood to gain little benefit from the medication but were still exposed to its risks of heart problems." In addition, the article reported:

> The research – gleaned from national databases – revealed that prescriptions of Merck's withdrawn arthritis therapy and other so-called COX-2 inhibitor drugs rose the fastest among patients with low or no

> risk of stomach bleeding, the complication that Vioxx and other Cox-2s were designed to prevent.

The article reported that the researchers "***blamed the phenomenon largely on drug companies' aggressive marketing campaigns*** and a new trend by doctors and their patients to view drugs designed for a specific purpose as 'one size fits all' miracle pills" (emphasis added).

358. On or about January 28, 2005, the SEC raised the level of its probe into Merck's handling of the VIOXX debacle into a full-fledged investigation. On May 12, 2005, the DOJ followed suit by announcing that it also had launched a formal criminal investigation into the acts of Merck and its executives with respect to VIOXX.

359. On February 11, 2005, *The New York Times*, in an article entitled "Marketing of Vioxx: How Merck Played Game of Catch-Up," reported on how Defendants, during the Class Period, sought to "neutralize' physicians who either supported Celebrex over VIOXX or took a negative views of VIOXX:

> Drug companies routinely try to woo doctors to prescribe or promote their drugs, taking them out to fancy meals, hiring them as speakers, or contributing to medical schools. ***But [] internal Merck documents offer a rare, behind-the-scenes look into the extremes of this process – one that may have blurred the line between legitimate promotion and offering inducements to doctors to prescribe a drug*** (emphasis added).

The article elaborated on the internal Company documents:

> The New York Times obtained the documents cited in this article – records that include First Warning Letter messages, memorandums and spreadsheets – through a public official. ***Some of those records involved physicians Merck sought to "neutralize," while others described promotional activities aimed at doctors not on that list.*** [Emphasize added.]

360. *The New York Times* article described how Defendants attempted to neutralize physicians whom Defendants believed had a negative view of VIOXX:

> In the "neutralize" documents written by a Merck marketing executive, company officials identified dozens of influential but "problem" physicians whom the company believed had either a negative view of Merck or Vioxx or were active boosters of Celebrex.
>
> To win them over, the documents show, Merck officials planned to offer them carrots like clinical trials, posts as consultants or give them grants.
>
> "Attached is the complete list of 36 physicians to neutralize with background information and recommended tactics," the marketing official wrote in an e-mail message.

> Merck officials insisted that all the activities they financed were "educational." But one part of a standardized form requesting payments to doctors had a somewhat less erudite tone. It read "Expected Outcome/Return on Investment."

361. According to FME-8, in the "early days" of VIGOR, FME-8 gave presentations on VIOXX on behalf of Merck. Merck, however, removed FME-8 from the "lecture circuit" after FME-8 made negative comments about VIOXX during presentations.

362. *The New York Times*, in a February 15, 2005 article entitled "Merck's Actions on VIOXX Face New Scrutiny," reported that "analysts estimate that Merck's total liabilities [stemming from the Vioxx debacle] could run as high as $30 billion."

363. Adding to Defendants' troubles due to their conduct throughout the Class Period, Defendants, in Merck's Form 10-K for 2004, filed on March 11, 2005, announced that they received notice that Merck's upper level excess insurers — which provide excess insurance potentially applicable to the VIOXX actions — have started an arbitration seeking in part to void all of their obligations related to VIOXX actions. The Form 10-K also stated:

> The Company currently anticipates that one or more of the Vioxx Product Liability Lawsuits may go to trial in the first half of 2005. The Company cannot predict the timing of any trial with respect to the VIOXX shareholder Lawsuits. The Company believes that it has meritorious

> defenses to the Vioxx Lawsuits and will vigorously defend against them. In view of the inherent difficulty of predicting the outcome of litigation, particularly where there are many claimants and the claimants seek indeterminable damages, the Company is unable to predict the outcomes of these matters, and at this time cannot reasonably estimate the possible loss or range of loss with respect to the Vioxx lawsuits.

364. Conspicuously absent from the Form 10-K was Defendants' materially false and misleading statement contained in its SEC filings during the Class Period that the "***Vioxx Lawsuits are completely without merit***." (Emphasis added.) Indeed, according to Merck's Form 10-Q for the first quarter 2005, as of March 31, 2005, Merck was a defendant in approximately 2,300 product liability lawsuits, which include approximately 4,600 plaintiff groups, and 110 putative class actions alleging personal injury claims, which concern the safety profile of VIOXX. Indeed, the juxtaposition between Defendants' Class Period statements, while they were misrepresenting and omitting to disclose the safety risks of VIOXX to preserve its earnings stream for the Company, that these suits were "completely without merit," and Defendants' post-Class Period statements, once the true safety risks of VIOXX were revealed and the drug was withdrawn and thus its income stream was at an end, that Merck could not "predict the outcomes of these matters," or estimate the possible loss to Merck, makes clear that Defendants' Class Period characterizations of these suits were false and misleading.

365. The Form 10-K also stated:

> The Company estimates that there were 105 million U.S. prescriptions written for VIOX from May 1999 through August 2004. Based on this estimate, the Company estimates that the number of patients who have taken VIOXX in the United States since its 1999 launch is approximately 20 million. The number of patients outside the United States who have taken Vioxx is undetermined at this time.

366. On March 10, 2005, *The Associated Press* reported that defendant Gilmartin "realized $34.8 million from exercising options in 2004, the year in which the company was roiled by the withdrawal of its blockbuster painkiller VIOXX." *The Associated Press* also reported that defendant Gilmartin's "total compensation for 2003 was about $3 million, including a $1.58 million salary and $1.4 million bonus."

367. On May 5, 2005, the House Government Reform Committee held a public hearing as part of its investigation, launched in November 2004, concerning the VIOXX withdrawal. The House Government Reform Committee's investigation shed further light on how Defendants trained Merck's sales representatives throughout the Class Period to engage in a campaign of deception that minimized the serious cardiovascular risks associated with VIOXX.

368. In response to the House Government Reform Committee's request that Merck produce a wide range of documents concerning VIOXX, Defendants produced over 20,000 pages of internal Company

documents, including course curricula, bulletins to the field, training manuals, Company talking points, memoranda among senior executives, and promotional materials for use with physicians. On May 5, 2005, the minority members of the House Committee issued the Congressional Memorandum, which summarized the "key documents" produced by Merck. Among other things, the Congressional Memorandum states:

> These documents provide an extraordinary window into how Merck trained its sales representatives and used them to communicate with physicians about Vioxx and its health risks. ***In fact, the documents may offer the most extensive account ever provided to Congress of a drug company's efforts to use its sales force to market to physicians and overcome health concerns*** (emphasis added).

369. As set forth in the Congressional Memorandum, "no interaction with physicians appears to have been too insignificant for instruction":

> Merck representatives were taught how long to shake physicians' hands (three seconds), how to eat their bread when dining with physicians ("one small bite size piece at a time"), and how to use "verbal and non-verbal" cues when addressing a physician to "subconsciously raise[] his/her level of trust." Merck instructed its representatives on the various personality types of doctors (including "technical," "supportive," and "expressive") and

> recommended targeted sales techniques for each type. ***And Merck rewarded its sales force with thousands of dollars in cash bonuses for meeting sales goals. The company assigned individual doctors a "Merck potential" and graded them on how often they prescribed Merck products*** (emphasis added).

370. The Congressional Memorandum discusses how Defendants trained Merck sales representatives, and provided them with false and misleading information, to "assuage any physicians concerns" that may have arisen as a result of "any public indication of VIOXX's safety risks":

> The documents describe in detail how Merck used this highly trained sales force to respond to reports of Vioxx's safety risks. The first public indication that Vioxx posed a heightened risk of heart attack and stroke came in March 2000, when Merck's VIGOR study showed a five-fold increase in the risks of heart attacks in patients on Vioxx compared to patients on naproxen. This study was followed by cautionary discussions of the cardiovascular risks of Vioxx at a meeting of an advisory committee to the Food and Drug Administration in February 2001, in a New York Times article in May 2001, and in a paper in the Journal of the American Medical Association in August 2001.

371. According to the Congressional Memorandum:

After each of these developments, Merck sent bulletins or special messages to its sales force, directing them to use highly questionable information to assuage any physician concerns. (emphasis added).

372. For example, the Merck documents show:

After Merck's VIGOR study reported increased heart attack risks, Merck directed its sales force to show physicians a "Cardiovascular Card" that made it appear that Vioxx could be 8 to 11 times safer than other anti-inflammatory drugs. This card omitted any reference to the VIGOR findings and was based on data FDA considered to be inappropriate for a safety analysis. [Emphasis in original.]

After the FDA advisory committee voted that physicians should be informed about the risks found in the VIGOR study, Merck sent a bulleting to its sales force that advised: "DO NOT INITIATE DISCUSSIONS OF THE FDA ARTHRITIS COMMITTEE . . . OR THE RESULTS OF THE . . . VIGOR STUDY." If physicians asked about the VIGOR study, Merck representatives were directed to respond, "I cannot discuss the study with you." [Emphasis in original.]

After *The New York Times* [on May 21, 2001] reported on the cardiovascular dangers of Vioxx, Merck instructed its

> **field staff to tell physicians that patients on other anti-inflammatory medications were eight times more likely to die from cardiovascular causes than patients on Vioxx.** The Merck bulleting told its sales force to show physicians the Cardiovascular Card and state: "Doctor, As you can see, Cardiovascular Mortality as reported in over 6,000 patients was Vioxx .1 vs. NSAIDS .8 vs. Placebo 0." [Emphasis in original.]

373. The Congressional Memorandum reports that internal Company documents provide precise details as to how Defendants instructed Merck sales representatives to mislead physicians concerning VIOXX's safety risks:

> [T]he documents suggest that Merck's sale representatives did not appropriately educate physicians about the research showing Vioxx's cardiovascular risks. ***To the contrary, it appears that Merck's highly trained sales force was instructed not to address the new research findings, but to emphasize outdated and misleading data that indicated Vioxx was safer than alternatives.*** The documents thus raise serious questions about the role played by Merck's representatives in physician prescribing of a risky drug (emphasis added).

374. The Congressional Memorandum also reveals that, pursuant to a Merck workbook entitled

Merck, Join the Club (Mar. 2001), sales representatives, when making a sales presentation, were only permitted to use medical journal articles "***when those articles presented Merck products in a favorable light.***" (Emphasis added.) According to the Congressional Memorandum:

> One course workbook instructed participants that medical journal articles relating to Merck drugs fell into two categories: "approved" and "background." "Approved" articles were those to be discussed with doctors because they "provide solid evidence as to why [doctors] should prescribe Merck products for their appropriate patients." In contrast, "background" articles were not approved for use with physicians. According to the workbook, "These articles may contain valuable background information, but this information cannot be used, and the articles cannot be referenced, during sales discussions with your customers." ***In fact, discussing unapproved background articles with physicians "is a clear violation of Company Policy."*** Merck instructed representatives to refer any questions about these articles to the medical services department (emphasis added).

375. The Congressional Memorandum reports how Defendants provided their sales representatives with materially false and misleading information concerning the results of the VIGOR Study and the safety of VIOXX:

Soon after the release of these results, physicians began asking Merck representatives whether Vioxx could cause heart attacks. ***On April 28, 2000, in a bulletin to "all field personnel with responsibility for Vioxx," Merck provided a "new resource" "to ensure that you are well prepared to respond to questions about the cardiovascular effects of Vioxx." The resource was the "Cardiovascular Card."***

The Cardiovascular Card was a tri-fold pamphlet containing data that supported the safety of Vioxx. One panel featuring the headline "Overall Mortality Rates," indicated that patients on Vioxx were 11 times less likely to die than patients on standard anti-inflammatory drugs, and 8 times less likely to die from heart attacks and strokes. [] Another panel indicated that the rate of heart attack among patients on Vioxx was less than half of the rate of patients receiving placebo and virtually identical to that of patients receiving other anti-inflammatory drugs.

Merck gave its representatives specific instructions on how to use the Cardiovascular Card. According to these instructions, Merck's representatives were to refer to the mortality data and "use this page to show physicians that in terms of mortality, which is most important to the physician and their

patients, the rate for total mortality and cardiovascular mortality was low."

The data presented in the Cardiovascular Card appears to have little or no scientific validity. The card did not present actual numbers of events or any statistical tests of significance, which are standard in medical communications. It also did not contain any information from the VIGOR study, the most recent study of cardiovascular safety in rheumatoid arthritis patients.

Instead, the card presented pooled data from clinical trials conducted prior to the drug's approval in osteoarthritis patients. ***For several reasons, however, these studies were not appropriate for an overall analysis of cardiovascular safety*** (emphasis added). For example:

- Vioxx's pre-approval studies involved few patients taking the doses of Vioxx that were linked to heart problems. According to FDA, fewer than 300 patients in these studies took as much as 50 mg per day of Vioxx for more than 6 months, compared to approximately 4,000 patients in the VIGOR study. As a result, the studies were not nearly as sensitive as VIGOR in detecting a possible problem with the drug.

- The pre-approval studies had been conducted to test the efficacy of the drug to treat pain, not to assess whether the drug caused heart attacks and

strokes. None of these early studies had included an expert assessment of whether adverse events were related to the cardiovascular system. Such an "adjudication" process improves the quality of the data and was part of the VIGOR study.

- The pre-approval studies varied widely, involving different doses, different patient populations, and different comparator drugs. In 1999, prior to Vioxx's approval, FDA had expressed serious concerns about combining these disparate studies in a single safety analysis.

- The analyses presented in the Cardiovascular Card were not drawn from a scientific paper. The card's two references included "data on file" at Merck and a brief research abstract from a 1999 meeting of the American College of Rheumatology.

- When given the opportunity, FDA scientists have expressed "serious concerns" about using the data summarized on the Cardiovascular Card to address cardiovascular safety. One FDA medical reviewer, in a briefing this week with Committee staff, said that the relevance of Vioxx's pre-approval studies to the drug's cardiovascular safety was "nonexistent" and that it would be "ridiculous" and "scientifically inappropriate" to present mortality comparisons from these trials to physicians.

- On May 1, 2000, Merck sent another bulletin to "all field personnel with responsibility for Vioxx." This bulletin instructed the sales force how to respond to a competitor's argument that "Vioxx

has an increased incidence of heart attacks compared to Celebrex." This response again involved advice to representatives to respond to physicians by "guiding them through the Cardiovascular Card."

376. The Congressional Memorandum also reports that, notwithstanding their awareness of the safety risks, Defendants provided financial incentives to Merck sales representatives to promote VIOXX:

> Notwithstanding the results of the VIGOR study, Merck's employees were given new financial incentives to sell Vioxx. In the spring of 2000, Merck launched the "2000 Field Incentive Plan for Vioxx." ***This plan promised reward to the company's hospital representatives, specialty representatives, and other sales representatives if the Vioxx share of the market for exceeded certain thresholds*** (emphasis added). As a bulletin to field staff explained:
>
> 1. Hit 51% . . . for at least one month by March 2000 and get $2,000!
>
> 2. Hit 55% . . . for at least one month between April and December 2000 and get $2,000!
>
> 3. Hit 61% . . . for at least one month between April and December 2000 and get $2,000!

377. On May 17, 2005, *Bloomberg News* reported that Credit Suisse First Boston, in an analyst report issued that day, reported the impact on Merck's business of VIOXX's non-existent commercial viability and inability to generate substantial revenues over the life of Merck's patent, which Defendants had concealed throughout the Class Period:

> Merck more than doubled long-term inventory after withdrawing the Vioxx painkiller in September, suggesting lower gross profit margins and a future write-off.
>
> * * *
>
> Merck's long-term inventory rose to $730 million over the past three quarters from $330 million, Credit Suisse analyst Catherine Arnold in New York wrote in a note to clients.

378. On May 24, 2005, United States District Judge Eldon Fallon, who is presiding over the pre-trial proceedings for the personal injury cases that were transferred to the United States District Court for the Eastern District of Louisiana, was told in a New Orleans courtroom that Merck may face as many as 100,000 cases against it over the VIOXX painkiller.

379. On May 31, 2005, *The New York Times*, in an article entitled "Despite Vow, Drug Makers Still Withhold Data," reported:

> Within the drug industry, companies are sharply divided about how much information to reveal, both about new studies and completed studies for drugs

> already being sold. The split is unusual in the industry, where companies generally take similar stands on regulatory issues.
>
> Eli Lilly and some other companies have posted hundreds of trial results on the Web, and pledged to disclose all results for all drugs they sell. ***But other drug makers, including Merck [] , release less information and are reluctant to add more, citing competitive pressures.***
>
> ***[T]he companies can hide negative trial results by refusing to publish studies, or by cherry-picking and highlighting the most favorable data from studies they publish*** (emphasis added).
>
> * * *
>
> Lilly has also posted the results of many completed studies to clinicalstudyresults.org, the website created last September by PhRMA. That site now contains some information on nearly 80 drugs that are already on the market. ***Both Lilly and Glaxo have posted detailed summaries of hundreds of studies . . . . Merck has posted none*** (emphasis added).

380. The next day, June 1, 2005, *The New York Times*, in an article entitled "Hiding the Data on Drug Trials," reported further details concerning certain pharmaceutical companies efforts to hide negative trial results from the public:

> By law, the companies are supposed to register important trials with a government Web site. Most manufacturers are complying, but the three big obfuscators — [including] Merck [] — are often getting around the requirement by not naming the drugs they are testing, instead using phrases like "an investigational drug." ***Merck was the worst offender, failing to provide a drug's name some 90 percent of the time*** (emphasis added).

381. Notwithstanding Defendants' failure to disclose the significant cardiovascular risk to the market, it is clear that Defendants were well aware during the Class Period of the significant number of heart attacks and cardiovascular events that were attributed to VIOXX. The FDA's Adverse Event Reporting System ("AERS") database is a computerized system for collecting and maintaining information about adverse events reported by drug manufacturers, health professionals, and others.

382. According to the AERS, during the Class Period, almost 15,400 adverse cardiac-related events experienced by persons taking VIOXX, including myocardial infarctions, cardiac arrests, and cardiac failures, which resulted in such serious outcomes as hospitalization, life threatening conditions, and even death, were reported to the FDA, as indicated below:

1999	2000	2001	2002	2003	2004	**Total**
331	2,248	2,899	2,915	2,435	4,452	**15,370**

383. It is widely understood that adverse events can be dramatically underreported. According to Brian Stom, author of a leading treatise on pharmacoepidemiology:

> It has been estimated that rarely more than 10% of serious ADRs, and 2-4% of non-serious reactions are reported to the British spontaneous reporting program. A similar estimate is that the FDA receives by direct report less than 1% of serious ADRs

Thus, Defendants well understood that the actual number of adverse events associated with VIOXX was significantly higher than the reported number.

384. In addition, according to FME-7, Merck maintained multiple databases that tracked, among other things, adverse events concerning Merck's drugs, as well as information on drugs that other pharmaceutical companies marketed, which was internally referred to as "competitive intelligence." The information, which was provided by, among others, doctors and sales representatives, was then used to produce reports for senior level management. According to FME-7, who was responsible for tracking information about VIOXX, on one day during the Class Period approximately 1,500 calls concerning issues related to VIOXX were received in FME-7's reporting area alone.

385. According to estimates in a study led by, Dr. David Graham, an FDA safety official, which were made public after Merck withdrew VIOXX from the market on September 30, 2004, use of VIOXX may have led to more than 139,000 heart attacks and cardiovascular events, 30% to 40% of which resulted in death.

DEFENDANTS' IMPROPER FAILURE TO DISCLOSE CONTINGENT LIABILITIES AND SIGNIFICANT RISKS AND UNCERTAINTIES

386. Defendants also attempted to deceive investors during the Class Period by failing, in Merck's financial statements, to disclose its contingent liabilities and significant risks and uncertainties related to VIOXX, in conformity with generally accepted accounting principles ("GAAP").

387. GAAP are recognized by the accounting profession and the SEC as the uniform rules, conventions, and procedures necessary to define accepted accounting practice at a particular time. GAAP requires that financial statements disclose contingencies when it is at least reasonably possible (i.e., a greater than slight chance) that a loss may have been incurred. SFAS No. 5, ¶ 10. The disclosure shall indicate the nature of the contingency and shall give an estimate of the possible loss, a range of loss, or state that such an estimate cannot be made. *Id.*

388. The SEC considers the disclosure of loss contingencies to be so important to an informed investment decision that it issued Article 10-01 of Regulation S-X [17 C.F.R. § 210.10-01], which provides that disclosures in interim period financial statements may be abbreviated and need not duplicate the disclosure contained in the most recent audited financial statements, except that "where material contingencies exist, disclosure of such matters shall be provided even though a significant change since year end may not have occurred."

389. In addition, GAAP requires that financial statements disclose significant risks and uncertainties

associated with an entity's business. *See Disclosure of Risks and Uncertainties*, Statement of Position No. 94-6.

390. In violation of GAAP, Merck's Class Period financial statements improperly failed to disclose that its sales of VIOXX exposed it to substantial risks and uncertainties, as detailed herein.

391. Nonetheless, Merck's financial statements, in violation of GAAP, failed to disclose the potential adverse consequences ensuing from such activity. Defendants falsely represented, in their SEC filings, that the Company's financial statements complied with GAAP.

392. Defendants also failed to disclose, in the Company's SEC filings, that the Company lacked adequate insurance to cover the known contingencies relating to VIOXX, including the personal injury litigation. According to Merck's October 21, 2004 press release, issued near the end of the Class Period, Merck has only about $630 million maximum coverage for the VIOXX personal injury lawsuits. As noted herein, analysts and others have estimated that the Company's total liability from such litigation might exceed $10 billion.

393. Instead of disclosing the very real and substantial contingencies caused by VIOXX personal injury claims, and other VIOXX litigation, in the Company's SEC filings, including the 2003 Form 10-K and the first quarter 2004 Form 10-Q, Defendants attempted to minimize the financial risk by referring generally to product liability and other suits and representing:

> There are various other legal proceedings, principally product liability and intellectual

property suits involving the Company, which are pending. While it is not feasible to predict the outcome of these proceedings or the proceedings discussed above, in the opinion of the Company, all such proceedings are either adequately covered by insurance or, if not so covered, should not ultimately result in any liability that would have a material adverse effect on the financial position liquidity or results of operations of the Company.

INSIDER SELLING

394. During the Class Period, the Insider Trading Defendants sold unusual and substantial amounts of Merck common stock from their personal holdings while in possession of adverse non-public information about VIOXX, and consequently, the adverse risks to Merck's financial prospects. Insider Trading Defendants held positions that made them privy to information about VIOXX's lack of a competitive advantage and safety problems. The sales occurred at prices as high as $90 per share (near the Class Period high closing price of $94.88). Many of the sales followed immediately the exercise of options to purchase Merck common stock at exercise prices as low as $13.625 per share and resulted in instantaneous net profits, in one day, of as much as $12 million or more. The Insider Trading Defendants' sales were unusual and suspicious, among other things, because of their size both in terms of the numbers of shares sold and the dollar amounts of the transactions. In addition, these individuals sold large portions of their holdings of Merck. Moreover, with one exception

(defendant Gilmartin purchased 10,000 shares at a price of $79.688 per share on November 3, 1999), none of these individuals made any open market purchases of Merck stock during the Class Period. Virtually the only acquisitions were through the exercise of options, as set forth below, and the purchase of relatively nominal amounts of stock through 401-K plans or automatically through the Merck Dividend Reinvestment Plan.

(a) Defendant Gilmartin

Defendant Gilmartin sold almost 52% of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
02/02/04	5,700	$47.71000	$271,947.00	1,054,990	$14.75130	$15,562,473.99
02/02/04	1,500	$47.73000	$71,595.00			
02/02/04	569,300	$47.50000	$27,070,250.00			
02/02/04	22,200	$47.60000	$1,056,720.00			
02/02/04	7,300	$47.61000	$347,553.00			
02/02/04	5,200	$47.62000	$247,624.00			
02/02/04	3,400	$47.63000	$161,942.00			
02/02/04	1,100	$47.65000	$52,415.00			
02/02/04	2,900	$47.69000	$138,214.00			
02/02/04	10,000	$47.70000	$477,000.00			
02/02/04	5,000	$47.81000	$239,050.00			
02/02/04	5,000	$47.90000	$239,500.00			
Total	664,925		$31,624,500.63	1,054,990		$15,562,473.99

(b) Defendant Frazier

Defendant Frazier sold almost **76%** of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
08/07/02	4,300	$47.80000	$205,540.00	6,826	$21.62500	$147,612.25
02/11/03	4,740	$54.58000	$258,709.20	6,824	$18.87500	$128,803.00
04/29/03	3,700	$57.09000	$211,233.00	600	$16.25000	$9,750.00
04/29/03	660	$57.15000	$37,719.00	6,000	$16.31250	$97,875.00
04/29/03	300	$57.14000	$17,142.00			
02/04/04	25,260	$48.97000	$1,236,382.20	12,660	$15.46220	$195,751.45
02/04/04				21,100	$20.08310	$423,763.41
Total	41,005		$1,967,325.40	54,010		$1,003,545.11

(c) Defendant Henriques

Defendant Henriques sold more than **94%** of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
07/31/00	600	$ 70.86200	$42,517.20	600	$ 21.20850	$ 12,725.10
07/31/00	2,600	$ 70.86200	$184,241.20	2,600	$ 21.62500	$ 56,225.00
07/31/00	2,600	$ 70.86200	$184,241.20	2,600	$ 18.87500	$ 49,075.00
10/27/00	600	$ 86.87500	$52,125.00	600	$ 16.25000	$ 9,750.00
10/27/00	4,000	$ 86.87500	$347,500.00	4,000	$ 16.31250	$ 65,250.00
05/07/02	2,700	$ 55.19000	$149,013.00	3,700	$ 16.31250	$ 60,356.25
05/07/02	300	$ 55.15000	$16,545.00	300	$ 16.31250	$ 4,893.75
10/27/03	15,000	$ 45.21000	$678,150.00	15,000	$ 20.08310	$ 301,246.50
10/27/03	1,000	$ 45.27000	$45,270.00			
10/27/03	4,100	$ 44.02000	$180,482.00			
10/31/03				6,100	$ 20.08310	$ 122,509.91
Total	33,500		$1,880,084.60	35,500		$ 682,028.51

(d) Defendant Lewent

Defendant Lewent sold more than **52%** of the shares she held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
07/27/00	20,000	$ 71.00000	$1,420,000.00	30,000	$ 13.62500	$ 408,750.00
10/25/00	600	$ 85.00000	$51,000.00	600	$ 21.20850	$ 12,725.10
10/25/00	33,000	$ 85.00000	$2,805,000.00	33,000	$ 21.87500	$ 721,875.00
07/26/01	20,000	$ 64.30030	$1,286,006.00	30,000	$ 21.87500	$ 656,250.00
02/06/02	53,000	$ 58.83210	$3,118,101.30	63,000	$ 25.91650	$ 1,632,739.50
05/01/02	18,700	$ 54.75000	$1,023,825.00	28,700	$ 18.87500	$ 541,712.50
05/01/02	800	$ 54.77000	$43,816.00	800	$ 18.87500	$ 15,100.00
05/01/02	500	$ 54.79000	$27,395.00	500	$ 18.87500	$ 9,437.50
10/29/02	45,000	$ 54.23340	$2,440,503.00	45,000	$ 18.87500	$ 849,375.00
02/11/03	25,000	$ 54.90000	$1,372,500.00	45,000	$ 18.87500	$ 849,375.00
04/30/03	600	$ 58.51210	$ 35,107.26	600	$ 16.25000	$ 9,750.00
04/30/03	25,000	$ 58.51210	$1,462,802.50	25,000	$ 18.56250	$ 464,062.50
05/02/03	25,000	$ 59.54000	$1,488,500.00	25,000	$ 18.56250	$ 464,062.50
12/01/03				25,000	$ 17.59500	$ 439,875.00
12/15/03				27,749	$ 17.59500	$ 488,243.66
Total	267,200		$16,574,556.06	379,949		$ 7,563,333.26

(e) Defendant Scolnick

Defendant Scolnick sold almost **61%** of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
10/25/00	600	$ 85.00000	$ 51,000.00	600	$ 21.20850	$ 12,725.10
10/25/00	600	$ 85.00000	$ 51,000.00	600	$ 16.25000	$ 9,750.00
10/25/00	180,000	$ 85.00000	$ 15,300,000.00	180,000	$ 18.56250	$ 3,341,250.00
10/25/00	200,000	$ 85.00000	$ 17,000,000.00	200,000	$ 21.18750	$ 4,237,500.00
Total	381,200		$ 32,402,000.00	381,200		$ 7,601,225.10

Total for All Defendants	1,360,060		$ 83,197,776.06	1,905,649		$ 32,412,605.96

(f) Defendant Anstice

Defendant Anstice sold almost **73%** of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
07/28/00	5,530	$ 72.68750	$ 401,961.88	10,000	$ 13.62500	$ 136,250.00
08/01/00	16,590	$ 73.50000	$ 1,219,365.00	30,000	$ 13.62500	$ 408,750.00
10/26/00	474	$ 87.03380	$ 41,254.02	600	$ 21.20850	$ 12,725.10
10/26/00	67,068	$ 87.03380	$ 5,837,182.90	81,000	$ 21.87500	$ 1,771,875.00
10/26/00	67,058	$ 87.03380	$ 5,836,312.56	81,000	$ 25.91650	$ 2,099,236.50
11/01/00	46,000	$ 90.00000	$ 4,140,000.00	60,000	$ 18.87500	$ 1,132,500.00
11/01/00	600	$ 90.00000	$ 54,000.00	600	$ 16.25000	$ 9,750.00
11/01/00	21,000	$ 90.00000	$ 1,890,000.00	21,000	$ 18.56250	$ 389,812.50
05/06/03	60,000	$ 58.81097	$ 3,528,658.00	60,000	$ 18.56250	$ 1,113,750.00
04/29/04	60,000	$ 47.35000	$ 2,841,000.00	60,000	$ 20.08310	$ 1,204,986.00
08/04/04	4,900	$ 44.75000	$ 219,275.00	87,699	$ 20.08310	$ 1,761,267.79
08/04/04	2,100	$ 44.76000	$ 93,996.00			
08/04/04	15,500	$ 44.77000	$ 693,935.00			
08/04/04	6,100	$ 44.78000	$ 273,158.00			
08/04/04	6,000	$ 44.79000	$ 268,740.00			
08/04/04	23,000	$ 44.80000	$ 1,030,400.00			
08/04/04	1,900	$ 44.81000	$ 85,139.00			
08/04/04	5,200	$ 44.82000	$ 233,064.00			
08/04/04	12,700	$ 44.83000	$ 569,341.00			
08/04/04	7,600	$ 44.84000	$ 340,784.00			
08/04/04	2,000	$ 44.86000	$ 89,720.00			
08/04/04	699	$ 44.87000	$ 31,364.13			
Total	432,019		$ 29,718,650.49	491,899		$ 10,940,902.89

(g) Defendant Clark

Defendant Clark sold over 89% of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
05/01/00	13,000	$ 69.37930	$ 901,930.90	17,000	$ 21.18750	$ 360,187.50
08/08/00	600	$ 72.37500	$ 43,425.00	600	$ 21.20850	$ 12,725.10
08/08/00	600	$ 72.37500	$ 43,425.00	600	$ 16.25000	$ 9,750.00
07/26/01	10,000	$ 76.68000	$ 765,800.00	10,000	$ 32.56250	$ 325,625.00
05/02/02	1,000	$ 54.99000	$ 54,990.00	1,000	$ 32.56250	$ 32,562.50
05/02/02	33,000	$ 54.70000	$ 1,805,100.00	36,000	$ 32.56250	$ 1,172,250.00
Total	58,200		$ 3,614,670.90	65,200		$ 1,913,100.10

(h) Defendant Colbert

Defendant Colbert sold almost 94% of the shares she held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
05/03/00	4,350	$ 71.00000	$ 308,850.00	4,350	$ 13.62500	$ 59,268.75
11/06/00	600	$ 90.00000	$ 54,000.00	600	$ 21.20850	$ 12,725.10
11/06/00	6,450	$ 90.00000	$ 580,500.00	6,450	$ 21.18750	$ 136,659.38
10/08/02				3,600	$ 21.62500	$ 77,850.00
10/08/02				3,600	$ 18.87500	$ 67,950.00
11/04/02	2,000	$ 55.00000	$ 110,000.00			
02/14/03	600	$ 53.50000	$ 32,100.00			
02/14/03	3,000	$ 53.48000	$ 160,440.00			
04/28/03	600	$ 57.12000	$ 34,272.00	600	$ 16.25000	$ 9,750.00
04/28/03	14,000	$ 57.11829	$ 799,656.00	14,000	$ 18.56250	$ 259,875.00
Total	31,600		$ 2,079,818.00	31,200		$ 624,078.23

(i) Defendant Cole

Defendant Cole sold almost **90%** of the shares she held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
10/31/01	1,600	$ 69.43750	$ 111,100.00	1,600	$ 21.50000	$ 34,400.00
04/29/04	2,532	$ 47.22000	$ 119,561.04	422	$ 20.37930	$ 8,600.06
04/29/04				2,110	$ 28.43630	$ 60,000.59
Total	4,132		$ 230,661.04	4,132		$ 103,000.66

(j) Defendant Distlerath

Defendant Distlerath sold **100%** of the shares she held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
01/31/00	4,800	$ 75.18750	$ 360,900.00	4,800	$ 13.62500	$ 65,400.00
05/09/00	600	$ 70.00000	$ 42,000.00	600	$ 21.20850	$ 12,725.10
05/09/00	5,400	$ 70.00000	$ 378,000.00	5,400	$ 21.87560	$ 118,125.00
10/25/00	3,676	$ 85.00000	$ 312,460.00	3,676	$ 21.62500	$ 79,493.50
10/25/00	600	$ 85.00000	$ 51,000.00	600	$ 16.25000	$ 9,750.00
10/25/00	3,674	$ 85.00000	$ 312,290.00	3,674	$ 18.87500	$ 69,346.75
Total	18,750		$ 1,456,650.00	18,750		$ 354,840.35

(k) Defendant Dorsa

Defendant Dorsa sold almost **95%** of the shares she held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
10/25/00	600	$ 85.00000	$51,000.00	600	$ 21.20850	$12,725.10
10/25/00	11,550	$ 85.00000	$981,750.00	11,550	$ 21.20850	$244,958.18
10/24/01	9,000	$ 67.21089	$604,898.00	9,000	$ 21.62500	$194,625.00
10/23/02				9,000	$ 18.87500	$169,875.00
10/24/02	2,500	$ 51.47000	$128,675.00			
04/24/03				600	$ 16.25000	$9,750.00
04/30/03	600	$ 57.57000	$34,542.00			
10/27/03	35,237	$ 45.22190	$1,593,484.00	35,237	$ 15.46220	$544,841.54
10/26/04	13,299	$ 30.39000	$404,156.61	63,299	$ 20.08310	$1,271,240.15
10/26/04	25,000	$ 30.38000	$759,500.00			
10/26/04	25,000	$ 30.35000	$758,750.00			
Total	122,786		$ 5,316,755.70	129,286		$ 2,448,014.96

(l) Defendant Elam

Defendant Elam sold over **24%** of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
05/03/00	4,000	$ 69.43750	$ 277,750.00	4,000	$ 23.95850	$ 95,834.00
05/03/00	1,500	$ 69.43750	$ 104,156.25	2,000	$ 18.75000	$ 37,500.00
05/03/00				2,000	$ 15.00000	$ 30,000.00
05/03/00				2,000	$ 21.50000	$ 43,000.00
Total	6,215		$ 381,906.25	10,000		$ 206,334.00

(m) Defendant B. Kelley

Defendant B. Kelley sold more than **97%** of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
02/01/00	19,950	$ 77.00000	$ 1,536,150.00	19,950	$ 13.62500	$ 271,818.75
10/25/00	600	$ 86.50000	$ 51,900.00	600	$ 21.20850	$ 12,725.10
10/25/00	26,700	$ 86.50000	$ 2,309,550.00	26,700	$ 21.87500	$ 584,062.50
10/25/00	24,000	$ 86.50000	$ 2,076,000.00	24,000	$ 21.62500	$ 519,000.00
10/25/00	50,000	$ 86.50000	$ 4,325,000.00	50,000	$ 18.87500	$ 943,750.00
Total	121,250		$ 10,298,600.00	121,250		$ 2,331,356.35

(n) Defendant W. Kelley

Defendant W. Kelley sold almost **62%** of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
02/12/03	1,265	$ 54.77000	$ 68,019.05	2,000	$ 18.75000	$ 37,500.00
02/09/04	2,110	$ 48.95000	$ 103,284.50	2,110	$ 11.21810	$ 30,000.19
Total	3,875		$ 171,303.55	4,110		$ 67,500.19

(o) Defendant Lofberg

Defendant Lofberg sold over **61%** of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
01/31/00	72,842	$ 75.00000	$ 5,463,150.00	72,842	$ 11.01500	$ 802,354.63
01/31/00	70,000	$ 75.00000	$ 5,250,000.00	70,000	$ 16.31250	$ 1,141,875.00
01/31/00	7,158	$ 75.00000	$ 536,850.00	7,158	$ 14.87500	$ 106,475.25
07/28/00	50,000	$ 73.00000	$ 3,650,000.00	50,000	$ 14.87500	$ 743,750.00
10/26/00	50,000	$ 87.00000	$ 4,350,000.00	50,000	$ 14.87500	$ 743,750.00
Total	250,824		$ 19,250,000.00	250,000		$ 3,538,204.88

(p) Defendant Wold-Olsen

Defendant Wold-Olsen sold almost 52% of the shares he held as of the beginning of the Class Period and options exercised during the Class Period.

Date	Number of Shares Sold	Price per Share	Proceeds	Number of Options Exercised	Exercise Price	Cost of Option Exercise
08/01/00	5,450	$ 73.52780	$ 400,726.51	5,950	$ 13.62500	$ 81,068.75
08/01/00	600	$ 73.52780	$ 44,116.68	600	$ 21.20850	$ 12,725.10
11/01/00	13,550	$ 89.87984	$ 1,217,871.88	19,050	$ 21.87500	$ 416,718.75
07/25/01	2,450	$ 64.39000	$ 157,682.00	9,525	$ 25.91650	$ 246,854.66
07/25/01	6,800	$ 64.35000	$ 437,580.00	9,525	$ 25.91650	$ 246,854.66
02/05/03	39,300	$ 55.00000	$ 2,161,500.00			
02/05/03				60,000	$ 18.87500	$ 1,132,500.00
07/30/03				600	$ 16.25000	$ 9,750.00
11/03/03	44,100	$ 44.75000	$ 1,973,475.00			
11/06/03				66,464	$ 17.59500	$ 1,169,434.08
08/03/04	10,000	$ 45.20000	$ 452,000.00	94,949	$ 20.08310	$ 1,906,870.26
08/03/04	16,400	$ 45.03000	$ 738,492.00			
08/03/04	5,000	$ 45.04000	$ 225,200.00			
08/03/04	7,500	$ 45.10000	$ 338,250.00			
08/03/04	15,000	$ 45.13000	$ 676,950.00			
08/03/04	5,000	$ 45.18000	$ 225,900.00			
08/03/04	7,500	$ 45.19000	$ 338,925.00			
Total	178,650		$ 9,388,669.07	266,664		$ 5,222,776.27

GRAND TOTALS	2,626,131		$ 166,356,151.68	3,300,139		$59,262,711.83

395. Defendant Gilmartin's sales of Merck common stock during the Class Period were suspicious in both timing and amount. At the start of the Class Period, defendant Gilmartin owned approximately 228,200 shares of Merck stock and 1,054,990 options to purchase Merck stock that were exercised during the Class Period. While during the Class Period he sold over 664,925 shares of stock, representing almost 52% of his holdings for gross proceeds of over $31,000,000.00, ***he***

did not sell a single share of stock in the five year period preceding the Class Period.[1]

396. Defendant Frazier's sales of Merck common stock during the Class Period were suspicious in both timing and amount. At the start of the Class Period, Defendant Frazier owned no shares of Merck stock, however, he did own approximately 54,010 options to purchase Merck stock that were exercised during the Class Period. While during the Class Period he sold over 41,005 shares of stock reflecting almost **76%** of his holdings for proceeds of over $1,900,000.00, ***he did not sell a single share of stock at any time before the Class Period.***[2]

397. Defendant Henriques' sales of Merck common stock during the Class Period were suspicious in both timing and amount. At the start of the Class Period, Henriques owned no shares of Merck stock, however he did own approximately 35,500 options to purchase Merck stock that were exercised during the Class Period. During the Class Period, Henriques sold 33,500 shares liquidating **94%** of his total holdings for proceeds of over $1,800,000.00.

398. Defendant Lewent's sales of Merck common stock during the Class Period were suspicious in both timing and amount. At the start of the Class Period, Lewent owned approximately 149,690 shares of Merck

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[1] "Holdings" includes shares held at the beginning of the Class Period plus options exercised during the Class Period.

[2] Although Frazier owned no shares of Merck stock prior to the Class Period, Frazier owned approximately 32,910 options to purchase Merck stock that were all exercisable before the Class Period. None of those options were exercised by Frazier.

stock and 379,949 options to purchase Merck stock that were exercised during the Class Period. During the Class Period, she sold 277,200 shares representing more than 52% of her holdings in Merck for proceeds in excess of $16,000,000.00, compared with pre-Class Period sales of 89,400 shares which represented almost 46% of her holdings.

399. Defendant Scolnick's sales of Merck stock were also suspicious in timing and amount. Within five days of defendant Gilmartin's statement in Merck's October 20, 2000 press release that defendants were "... proud of the achievements of our newest medicine VIOXX" — driving the price of Merck from $81.87 per share on October 20, 2000 to $87.31 per share on October 25, 20000 — Scolnick sold 381,200 shares for $85 per share representing over 60% of his total Merck holdings for proceeds of over $32 million. Scolnick's sales conveniently occurred at a time when Merck's stock price was trading close to its Class Period high of approximately $94.88 on November 29, 2000

THE FRAUD-ON-THE-MARKET DOCTRINE

400. Plaintiffs herein are entitled to a presumption that they relied upon the integrity of the market with respect to their open-market purchases of Merck securities. Plaintiffs allege that: (i) Defendant made public misrepresentations; (ii) the misrepresentations were material; (iii) Defendants' misrepresentations would induce a reasonable, relying investor to misjudge the value of the shares; (iv) Plaintiffs traded Merck shares between the time the misrepresentations were made and the time the truth was revealed; and (v)

for the following reasons, Merck shares were traded on an efficient market:

(a) Merck's stock met the requirements for listing, and was listed and actively traded on the NYSE, a highly efficient and automated market;

(b) As a regulated issuer, Merck filed periodic and other public reports with the SEC and the NYSE;

(c) Merck regularly communicated with public investors by means of established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Merck was followed by numerous securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and customers of their respective brokerage firms. Those reports were publicly available and entered the public marketplace.

401. As a result of the foregoing, the market for Merck's securities promptly digested current information regarding Merck from all publicly available sources and reflected such information in Merck's stock price. Under these circumstances, all purchasers of Merck's securities during the Class Period suffered similar injury through their purchase of Merck's securities at artificially inflated prices, which fell as the truth concerning VIOXX became known, and a presumption of reliance applies.

NO SAFE HARBOR

402. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Merck who knew that those statements were false when made.

COUNT I

VIOLATIONS OF SECTION 10(B) OF THE EXCHANGE ACT AND RULE 10B-5 PROMULGATED THEREUNDER AGAINST DEFENDANT MERCK AND THE INDIVIDUAL DEFENDANTS

403. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

404. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was

intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Merck's securities; and (iii) cause Plaintiffs and other members of the Class to purchase Merck's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants took the actions set forth herein.

405. Merck and the Individual Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and omitted to state material facts necessary to make the statements not materially misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Merck's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued as primary participants in the wrongful and illegal conduct charged herein.

406. In addition to the duties of full disclosure imposed on Defendants as a result of their making of affirmative statements and reports, or participation in the making of affirmative statements and reports to the investing public, Defendants had a duty to disseminate promptly truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC as embodied in SEC Regulation S-X (17 C.F.R. § 210.01 et seq.) and Regulation S-K (17 C.F.R. § 229.10 *et seq.*) and other SEC regulations, including accurate and truthful information with respect to the Company's business operations, products, performance, and prospects so that the market price of

the Company's securities would be based on truthful, complete and accurate information.

407. Merck and the Individual Defendants, individually and in concert, directly and indirectly, by the use of the means and instrumentalities of interstate commerce and of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the products, business, operations, and prospects of Merck as specified herein.

408. Merck and the Individual Defendants employed devices, schemes, and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Merck's value, and performance, and continued substantial growth, which included the making of or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Merck and its products, business, operations, and prospects in the light of the circumstances under which they were made, not materially misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Merck's securities during the Class Period.

409. Merck and each of the Individual Defendants' are primarily and directly liable for the wrongful conduct alleged herein.

410. Merck and the Individual Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with

reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. The Defendants' material misrepresentations and omissions were done knowingly or recklessly and for the purpose and effect of concealing the truth with respect to Merck's products, performance, and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' material misstatements throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

411. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market prices of Merck's securities were artificially inflated during the Class Period. In ignorance of the fact that market prices of Merck's publicly-traded securities were artificially inflated, and relying directly or indirectly on the materially false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class purchased Merck securities during the Class Period at artificially high prices, which fell precipitously as the truth concerning VIOXX became known, and were damaged thereby.

412. At the time of said misrepresentations and omissions, Plaintiffs and the other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth with respect to the business, products, and prospects of Merck, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased Merck securities, or, if they had purchased such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid. The material misrepresentations and omissions alleged herein were the direct and proximate cause of the losses suffered by Plaintiffs and other members of the Class. The price of Merck securities declined as the market became aware of the truth concerning VIOXX, which had been concealed and misrepresented by Defendants.

413. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

414. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases of the Company's securities during the Class Period.

COUNT II

VIOLATIONS OF SECTION 20(A) OF THE EXCHANGE ACT AGAINST THE INDIVIDUAL DEFENDANTS

415. Plaintiffs repeat and realleges each and every allegation contained above as if fully set forth herein.

416. The Individual Defendants acted as controlling persons of Merck within the meaning of Section 20(a) of the Exchange Act as alleged herein: (i) the Individual Defendants were high-level executives and directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) their responsibilities and activities as senior officers and directors of the Company, the Individual Defendants were privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, and reports; (iii) their significant personal contact and familiarity with the other defendants, the advise of and access to other members of the Company's management team, internal reports, and other data and information about the Company's business, operations, and products at all relevant times; (iv) their knowledge that the Company's disseminated information to the investing public that materially false and misleading; (v) their participation in and awareness of the Company's business and operations; (vi) their power to influence and control, and exercise of that influence and control, directly or indirectly, over the decision-making of the Company, including the content and dissemination of the various statements that Plaintiffs allege were materially false and misleading; (vii) their receipt of, or unlimited access

to the Company's reports, press releases, public filings, and other statements alleged by Plaintiffs to be materially misleading prior to or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected; and (viii) their direct and supervisory involvement in the day-to-day operations of the Company. Based upon the foregoing, the Individual Defendants had the power to control or influence the transactions giving rise to the claims alleged herein, and exercised the same.

417. As set forth above, Merck violated Section 10(b) and Rule 10b-5 by its wrongful acts and omissions as alleged in this Complaint, and is liable for such violations to Plaintiffs and the Class. By virtue of their positions as controlling persons, the Individual Defendants are also liable pursuant to Section 20(a) of the Exchange Act.

COUNT III

VIOLATIONS OF SECTION 20A OF THE EXCHANGE ACT AGAINST THE INSIDER TRADING DEFENDANTS

418. Plaintiffs repeat and reallege each allegation contained above as if fully set forth herein.

419. This claim is asserted by those Plaintiffs who purchased contemporaneously with the sale of Merck securities by the Insider Trading Defendants (the "20A Plaintiffs") on behalf of themselves and other Class members pursuant to § 20A of the Exchange Act, for purchases of Merck stock made contemporaneous with the sale of Merck stock by insiders in possession of

material, non-public adverse information that affected the value of those Merck shares.

420. During the Class Period, defendants Gilmartin, Frazier, Henriques, Lewent, Scolnick, Anstice, Clark, Colbert, Cole, Distlerath, Dorsa, Elam, B. Kelley, W. Kelley, Lofberg, and Wold-Olsen, *i.e.*, the Insider Trading Defendants, executed options and sold Merck common stock while in possession of material, non-public adverse information, in violation of § 10(b) and § 20(a) of the Exchange Act, as more fully alleged herein.

421. 20A Plaintiffs and the members of the Class purchased Merck common stock on national securities exchanges contemporaneously with sales of Merck common stock by the Insider Trading Defendants while such defendants were in possession of material, non-public adverse information regarding the safety profile of Merck's prescription painkilling drug VIOXX and have been damaged by reason of the violations of § 20A alleged herein. The Insider Trading Defendants, while in possession of material, non-public adverse information from defendant Merck, in violation of §20A(c) of the Exchange Act, 15 U.S.C. § 78t-1(a), engaged in at least 140 individual sales transactions in Merck securities on at least 51 different dates within the Class Period.

422. Defendant Merck, acting through its officers and agents, is liable under §20A(c) of the Exchange Act for communicating material, non-public adverse information to certain of the Insider Trading Defendants, which in turn communicated to other insiders, thereby enabling them to trade on such information and damage the 20A Plaintiffs and the other members of the Class who purchased while the Insider

Trading Defendants were contemporaneously selling Merck shares.

423. The Insider Trading Defendants, by reason of their status as controlling persons pursuant to §20(a) of the Exchange Act, are liable pursuant to §20A(b)(3) of the Exchange Act for Merck's violations of the Exchange Act as more fully alleged herein. Further, the Insider Trading Defendants are liable pursuant to §20A(c) of the Exchange Act by reason of their communication of material, non-public adverse information to other insiders regarding Merck.

424. By reason of the violations of §20A of the Exchange Act alleged herein, the Insider Trading Defendants are jointly and severally liable to 20A Plaintiffs and the members of the Class who purchased shares of Merck common stock contemporaneously with the sales of the Insider Trading Defendants of Merck common stock during the Class Period, for the communication and resulting transactions based on material, non-public adverse information regarding Merck.

425. By virtue of the foregoing, the Insider Trading Defendants have violated Section 20A of the Exchange Act.

426. As a direct and proximate result of the Insider Trading Defendants' wrongful conduct, the 20A Plaintiffs and the other subject members of the Class seek disgorgement of the Insider Trading Defendants' profits from their transactions in Merck securities during the Class Period.

COUNT IV

VIOLATIONS OF SECTION 11 OF THE SECURITIES ACT AGAINST DEFENDANT MERCK AND THE DIRECTOR DEFENDANTS

427. Plaintiffs Kanter and Park East incorporate by reference all paragraphs above, except the allegations of fraud and scienter.

428. This Count is brought by Plaintiffs Kanter and Park East, pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k, on behalf of themselves and all Class members who acquired shares of Merck common stock through the MSIP, against defendant Merck and the Director Defendants.

429. Plaintiffs Kanter and Park East acquired shares of Merck common stock through the MSIP pursuant to the MSIP Registration Statement.

430. Defendant Merck is the registrant for the shares sold pursuant to the MSIP. Each of the Director Defendants signed MSIP Registration Statement and was a director of Merck at all relevant times.

431. The MSIP Registration Statement and documents incorporated by reference therein "contained . . . untrue statement[s] of . . . material fact or omitted to state . . . material fact[s] required to be stated therein or necessary to make the statements therein not misleading" in violation of § 11 of the Securities Act as more fully set forth herein. The untrue statements were materially incorrect on the date the Registration Statement became effective and remained incorrect thereafter.

432. At the times they acquired Merck common stock through the MSIP, Plaintiffs Kanter and Park East and other members of the Class did not know of the untruths and omissions complained of herein.

433. Class members who acquired the common stock that is the subject of this Count after Merck had made generally available to its security holders an earning statement covering a period of at least 12 months beginning after the effective date of the Registration Statement acquired such stock relying on: (i) the untrue statements in the Registration Statement or (ii) the Registration Statement and not knowing of the omissions complained of herein.

434. With respect to the untrue statements and omissions complained of in this Count, the Director Defendants did not conduct "a reasonable investigation" and did not have "reasonable ground to believe at the time such [materially incorrect] part[s] of the registration statement became effective, that the statements therein were true and that there was no omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading" as required by § 11(b)(3) of the Securities Act

435. This action was brought within one year after Plaintiff and members of the Class who acquired shares of Merck common stock through the MSIP discovered, or by the exercise of reasonable diligence should have discovered, the untrue statements and omissions complained in this Count, and no more than three years after the common stock that is the subject of this Count was *bona fide* offered to the public.

436. As a result of the foregoing, Merck and the Director Defendants have violated § 11 of the Securities Act and Plaintiffs Kanter and Park East and the Class members who acquired shares of Merck common stock through the MSIP have been damaged.

COUNT V

VIOLATIONS OF SECTION 12(A)(2) OF THE SECURITIES ACT AGAINST DEFENDANT MERCK AND THE INDIVIDUAL AND DIRECTOR DEFENDANTS

437. Plaintiffs Kanter and Park East incorporate by reference all paragraphs above, except allegations of fraud and scienter.

438. This Count is brought by Plaintiffs Kanter and Park East pursuant to § 12(a)(2) of the Securities Act, 15 U.S.C. ¶771(a)(2), against defendant Merck and the Director Defendants and the Individual Defendants on behalf of herself and all Class members who purchased shares of Merck common stock through the MSIP.

439. The Registration Statement, and documents incorporated therein, and the Prospectuses, and documents incorporated therein, each constituted a "prospectus" within the meaning of § 12(a)(2) of the Securities Act. Each prospectus included untrue statements of material facts and omitted to material facts necessary in order to make statements in the Prospectus, in light of the circumstances under which they were made, not misleading.

440. As set forth more fully herein, through the MSIP defendant Merck and the Director Defendants and the Individual Defendants offered and sold Merck common stock, by the use of means and instruments of transportation and communication in interstate commerce and the mails, by means of a prospectus, which included untrue statements of material facts and omitted to state material facts necessary in order to make statements in the prospectus, in light of the circumstances under which they were made, not misleading.

441. The defendants named in this Count solicited the purchase of Merck common stock, through the MSIP, motivated at least in part by a desire to serve their own financial interests or those of the issuer, Merck. Among other things, defendants signed and/or participated in the preparation of a prospectus used to sell Merck common stock through the MSIP.

442. Plaintiffs Kanter and Park East and other members of the Class who purchased shares of Merck common stock through the MSIP did not know of the untruths and omissions complained of this Count when they purchased such shares.

443. By reason of the foregoing, defendant Merck, the Director Defendants, and the Individual Defendants have violated § 12(a)(2) of the Securities Act.

444. Plaintiff Kanter and members of the Class who purchased shares of Merck common stock through the MSIP are entitled to recover the consideration paid for such shares with interest thereon, less the amount of any income received thereon, and hereby tender such shares. Members of the Class who purchased shares of Merck common stock through the MSIP and who no

longer own such shares are entitled to damages, as allowed by § 12(a)(2) of the Securities Act.

445. This action was brought within one year after Plaintiffs Kanter and Park East and Class members who purchased shares of Merck common stock through the MSIP discovered, or by the exercise of reasonable diligence should have discovered, the untrue statements and omissions complained in this Count and no more than three years after they purchased such shares.

COUNT VI

VIOLATIONS OF SECTION 15 OF THE SECURITIES ACT AGAINST THE INDIVIDUAL DEFENDANTS

446. Plaintiffs Kanter and Park East incorporate by reference paragraphs alleged in Counts IV and V above as though fully set forth herein.

447. Plaintiffs Kanter and Park East bring this Count pursuant to Section 15 of the Securities Act against the Individual Defendants.

448. The Individual Defendants were controlling persons of Merck within the meaning of Section 15 of the Securities Act by reason of their respective management positions in Merck, and/or their membership on Merck's Board of Directors, and/or their stock ownership, and/or their participation throughout the Class Period in the day-to-day affairs of Merck. Because of their positions in the Company and/or their stock ownership, and/or because of their positions on the Merck Board of Directors, these Defendants had the requisite power to

directly or indirectly control or influence the specific corporate policy that resulted in the unlawful acts and conduct alleged herein.

449. By reason of the foregoing, the Individual Defendants have violated Section 15 of the Securities Act, and are liable to Plaintiffs Kanter and Park East and the other members of the Class who purchased Merck common stock during the Class Period through the Merck MSIP.

COUNT VII

DIRECTORS, OFFICERS, AND CORPORATE LIABILITY POLICY DIRECT ACTION INSURANCE CLAIM AGAINST THE INSURER DEFENDANTS

450. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

451. The Insurer Defendants issued directors, officers and corporate liability polices. These policies provided liability coverage to at least the Individual Defendants and the Director Defendants as more fully set forth in the provision of the polities.

452. During the policy or extended discovery period, the Company and/or certain of the Individual Defendants and/or Director Defendants became aware of occurrences which subsequently gave rise to the claims being asserted herein, and during the policy or extended periods, one or more of the Insurer Defendants received notice of such occurrences, resulting in coverage under the provision of the applicable directors', and officers' liability insurance policies. Alternatively,

the claims were asserted against Merck, the Individual Defendants and/or the Director Defendants during the policy period, and notice was timely given to one of more of the Insurer Defendants of such claims resulting in coverage under the policies.

453. Accordingly, pursuant to the Louisiana Direct Action Statue, Louisiana Statutes 22:655, Plaintiffs and the other members of the Class are entitled to recover directly from the Insurer Defendants the damages suffered as a result of the allegations set forth herein.

WHEREFORE, Plaintiffs pray for relief and judgment, on behalf of themselves and the Class, as follows:

(a) Declaring this action to be a proper class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein and declaring Plaintiffs to be proper Class representatives;

(b) Awarding all Plaintiffs and the members of the Class compensatory damages in an amount to be determined at trial;

(c) Awarding Plaintiffs Kanter and Park East and members of the Class who participated in Merck's MSIP damages and/or rescission in accordance with Sections 11, 12(a)(2), and 15 of the Securities Act;

(d) Awarding 20A Plaintiffs and other members of the Class who purchased Merck shares contemporaneously with the sales by the Insider Trading Defendants of Merck securities, the profits that Defendants realized as a result of those insider sales;

(e) Awarding all Plaintiffs and the members of the Class pre-judgment and post-judgment interest, as well as their attorneys' fees, expert witness fees and other costs;

(f) Awarding such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: June 14, 2005

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

Case No.: 03-CV-3125
Filed August 9, 2004

FRANK PRINGLE
v.
MERCK & CO., INC., ET AL.

CONSOLIDATED AND SECOND AMENDED CLASS ACTION COMPLAINT

* * * * *

ADDITIONAL SCIENTER ALLEGATIONS

199. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws.

200. The Individual Defendants were senior executives and directors of Merck and were directly

involved in the day-to-day management of its business at the highest levels. They ran Merck as "hands-on" managers, dealing with important issues facing Merck's business, such as the production and marketing of VIOXX. Defendants had direct responsibilities with respect to the matters alleged herein. For example, Defendant Scolnick was President of Merck Research Laboratories, and spoke at analyst conferences about VIOXX.

201. The results of the VIGOR Study made clear that, notwithstanding Defendants' repeated public denials, VIOXX was associated with an increased risk of heart attacks.

202. The SEC Warning Letters also put Defendants on notice of the serious risks associated with VIOXX, and that Defendants' public statements concerning the safety of VIOXX were false and misleading.

203. Numerous articles and reports published during the Class Period, as referred to herein, discussed VIOXX's adverse cardiovascular risks. Although Defendants consistently contended such reports were wrong, they clearly put Defendants on notice of the serious problems discussed herein.

204. Defendants were required by law to report to the FDA adverse events reported to Defendants. The FDA has a computerized system (AERS), described above, for storing information concerning adverse events, including information reported by health professionals and others to drug manufacturers. In addition, Merck has its own system for monitoring information, including information concerning adverse

events, about its products, including VIOXX, and its competitors' products.

205. That prior to the FDA approving Merck's NDAs for VIOXX, and well before the Class Period, Defendants conducted extensive studies and analyses of the Drug, including clinical studies involving humans. According to Defendants' November 23, 1998 press release:

> The [NDA] application included results from 68 studies and nearly 10,000 patients that evaluated Vioxx.

206. The seriousness of the cardiovascular risks created by VIOXX, including the risk of death, further compels an inference of scienter.

207. Numerous federal and state lawsuits filed as early as 2001 agains Merck with respect to VIOXX, including more than 200 personal injury lawsuits, alleging, among other things, that VIOXX caused significant personal injuries, and even death, also evidence Defendants' knowledge.

208. In addition to all of the foregoing, Defendants had powerful motives and the opportunity to perpetuate the fraudulent scheme and course of business described herein.

209. The central importance of VIOXX to the overall performance and prospects of the Company further supports a strong inference of scienter:

(a) That the patents on three of Merck's best selling products were set to expire made the success of VIOXX all the more critical.

(b) According to Merck's filings with the SEC. VIOXX was Merck's second largest selling drug for each of 2000, 2001, and 2002, accounting for billions of dollars of worldwide sales. Defendants themselves described VIOXX as a "driving force" behind the Company's performance. Accordingly, Defendants had an obvious motive to delay as long as possible full disclosure of the truth about the safety of the Drug to avoid jeopardizing sales of the Drug, which were so critical to the Company's performance.

210. Defendants were also motivated to conceal VIOXX's adverse cardiovascular risks from the market because of problems that Merck was experiencing with ARCOXIA, the Company's planned successor to VIOXX. On March 15, 2002, Defendants were forced to withdraw the original NDA for ARCOXIA. Thus, Defendants had a clear motive to keep the market in the dark for as long as possible about the cardiovascular risks of VIOXX so that Merck could continue to reap profits from the Drug.

211. Given that naproxen and other traditional NSAIDs sell for a fraction of the price of VIOXX, and that VIOXX is no more effective than traditional NSAIDs at treating inflammation and pain, the disclosure of the serious safety risks associated with VIOXX would have significantly jeopardized its marketability.

212. Similarly, any disclosure of VIOXX's cardiovascular risks would have put it at a strong competitive disadvantage with respect to Celebrex, which was being actively promoted by Pfizer and Monsanto and had the advantage of being approved by the FDA approximately six months before VIOXX was approved.

213. In the face of numerous actual and potential lawsuits, Defendants also were motivated to conceal and downplay the safety problems associated with VIOXX to avoid potentially devastating liability.

214. As detailed below, Defendants profited personally from the wrongdoing alleged herein by selling more than 1.1 million shares of Merck stock at artificially inflated prices, as detailed below.

215. Defendants clearly had the opportunity to commit the fraudulent conduct alleged herein. The Individual Defendants were all members of the Company's senior management who controlled its public statements during the Class Period.

* * * * *

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MDL No. 1658 (SRC)
Case No. 3:05-CV-01151-SRC-MF
Case No. 3:05-CV-02367-SRC-MF

IN RE MERCK & CO., INC., SECURITIES, DERIVATIVE & "ERISA" LITIGATION

CORRECTED CONSOLIDATED FIFTH AMENDED CLASS ACTION COMPLAINT

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* * * * *

I. PRELIMINARY STATEMENT

1. Plaintiffs bring this federal securities class action on behalf of themselves and a proposed class of persons and entities (the "Class") who purchased or acquired Merck securities between May 21, 1999 and October 29, 2004, inclusive (the "Class Period").

2. Throughout the Class Period, Merck and the Officer and Director Defendants made materially false and misleading statements of fact and belief concerning the safety profile and commercial viability of Merck's purported "blockbuster" drug VIOXX (a/k/a MK 966 or

"rofecoxib"). As a result of Defendants' materially false and misleading statements, during the Class Period the value of Merck securities was significantly inflated. When the truth concerning VIOXX's safety and commercial viability finally began to emerge, the value of Merck securities fell sharply, causing Plaintiffs and the Class members to suffer massive damages. In contrast, during the same period, the Insider Trading Defendants (identified in ¶ 43 below) as a group sold millions of shares of their own personal holdings of Merck stock, reaping lucrative insider selling profits in excess of $94 million, including more than $20.9 million, $24.8 million and $20.85 million, respectively, reaped by Merck's CEO (defendant Raymond Gilmartin), its Executive Vice President for Science & Technology (defendant Edward Scolnick), and the President of Merck's Human Health Prescription Division (defendant David Anstice).

3. VIOXX is a non-steroidal anti-inflammatory drug ("NSAID") intended for use in the treatment of arthritis and other acute pain. Traditional NSAIDs, such as aspirin, ibuprofen and naproxen, function by inhibiting two enzymes: cyclooxygenase-1 ("COX-1"), which is associated with the maintenance of protective gastrointestinal ("GI") mucus, and cyclooxygenase-2 ("COX-2"), which is associated with the response to pain and inflammation. Unfortunately, the inhibition of COX-1 (and resulting inhibition of protective gastrointestinal mucus) by traditional NSAIDs can cause serious GI side effects, which result in tens of thousands of serious injuries and deaths each year in the United States alone. In developing VIOXX, Merck sought to develop a drug that would selectively suppress only COX-2 (thereby suppressing pain and inflammation) *without* suppressing COX-1 (thereby *avoiding* the adverse GI side effects associated with traditional NSAIDs).

4. There is an enormous worldwide market (estimated to be worth multiple billions of dollars *per year*) for a painkilling drug that lacks the adverse GI side effects of traditional NSAIDs, because patients suffering from diseases that cause chronic pain, such as arthritis, would be inclined to take such a drug on a daily basis. Consequently, Defendants and the market viewed VIOXX as a potential "blockbuster" drug.

5. The importance of VIOXX's commercial success to Merck could hardly be overstated, because at all relevant times Merck desperately needed to be able to market a major new drug whose revenue would be sufficient to off-set the more than $5 billion in annual revenue that Merck would be losing as *five* of Merck's existing drugs (Vasotec, Pepcid, Mevacor, Prilosec and Prinivil) were all scheduled to go "off patent" (*i.e.*, lose their patent protection) between August 2000 and the end of 2001. According to published reports, Merck's ability to survive as a separate company might even have been at risk if VIOXX failed to achieve and maintain blockbuster status.

6. Beginning with its press release of May 21, 1999 (the first day of the Class Period), in which Merck trumpeted the news that the FDA had approved VIOXX for the treatment of osteoarthritis, throughout the Class Period Defendants repeatedly touted VIOXX's safety profile, sales and commercial prospects in press releases, public statements, Merck prepared medical journal articles, and filings with the SEC. Defendants repeatedly claimed, *inter alia*, that VIOXX was a "key growth driver" for Merck, that it had "robust" growth prospects for the treatment of arthritis and numerous other ailments, and that VIOXX sales would generate billions of dollars annually well into the future. By 2003, VIOXX

was Merck's second bestselling drug (with annual sales of $2.5 billion), and Merck readily acknowledged that without VIOXX Merck "would be a very different company."

7. As set forth in detail below, however, Defendants' Class Period public statements concerning VIOXX were materially false or misleading, omitted to disclose numerous material facts necessary to make their statements not materially misleading, and/or misrepresented Merck's and its senior officers' and scientists' actual beliefs concerning VIOXX's safety and, consequently, its commercial prospects. Indeed, from the very start of the Class Period in May 1999, when Merck first announced the news of the FDA's approval of VIOXX, unbeknownst to the public, Merck internally had grave concerns that VIOXX caused serious cardiovascular ("CV") side effects, including myocardial infarction ("MI") (*i.e.*, heart attacks) and strokes. These serious concerns about VIOXX's CV risks were based on the research of one of Merck's own consultants (Dr. Garret FitzGerald) — and the corroborating views privately provided to Merck by one of the Company's other prominent consultants (Dr. John Oates) — which showed, based on urine analyses, that VIOXX upset one of the body's internal mechanisms by (a) suppressing prostacyclin (a chemical that occurs naturally in the body which *widens* blood vessels and *inhibits* blood clotting) while *simultaneously* (b) having *no* impact on the body's production of thromboxane (a chemical that *narrows* blood vessels and potently *promotes* blood clots).

8. Accordingly, as confirmed in internal Merck emails from the late 1990's that were only disclosed after the Class Period, as a result of Merck's "great concern" that VIOXX increases the risk of adverse CV events —

and that any clinical findings to that effect would "kill [the] drug" — Merck scientists discussed how to design Merck's major clinical trials of VIOXX to minimize the risk that they would call attention to the extent of VIOXX's adverse CV (or "prothrombotic") side effects. Nonetheless, by no later than February 1998 Merck was in possession of a non-public internal analysis indicating that patients in its VIOXX clinical trials had significantly higher rates of serious adverse CV events compared to patients taking placebo, including a statistically significant *216%* increased risk for adverse CV events among women taking VIOXX.

9. Although the FDA approved VIOXX in May 1999, Merck and the Officer Defendants knew that (a) the FDA would not allow it to market VIOXX with a label stating that VIOXX posed a significantly lower risk of adverse GI side effects than traditional NSAIDs unless and until Merck conducted a large scale gastrointestinal trial demonstrating that this was true, and (b) VIOXX's commercial prospects would be sharply curtailed if Merck failed to obtain an FDA-approved label affirming VIOXX's favorable GI safety. Accordingly, even though Merck had put off conducting a large-scale GI trial in 1997 (primarily due to its fears that such a trial would highlight VIOXX's prothrombotic side effects), in January 1999 — by which time Merck was reasonably confident that it would obtain initial FDA approval of VIOXX — Merck commenced a large scale VIOXX Gastrointestinal Outcomes Research ("VIGOR") trial. The VIGOR trial compared the results of a large patient group taking VIOXX to a similarly large patient group taking naproxen (a traditional NSAID marketed in the U.S. under the brand names Aleve and Naprosyn).

10. Merck designed the VIGOR study to minimize the likelihood that the results would show that VIOXX was prothrombotic, but the results of the VIGOR study nonetheless showed that patients taking VIOXX had a statistically significant higher incidence of adverse CV events (particularly heart attacks) than patients taking naproxen. Reviewing these results, Merck and the Officer Defendants concluded that VIOXX was prothrombotic, as they had feared. As defendant Edward Scolnick, Merck's Executive Vice President for Science and Technology and Merck's chief research scientist, acknowledged in a March 9, 2000 internal email to three other senior Merck scientists (including Merck's Executive Director of Clinical Research, defendant Alise Reicin):

> I just received and went through the [VIGOR] data.... ***The [adverse] CV [cardiovascular] events are clearly there.... It is a shame*** but it is a low incidence ***and it is mechanism based as we worried it was***. [Dr. John] Oates and [senior Merck scientists] Alan [Nies] and Barry [Gertz] were right about the metabolite meanings ie urine Pg [prostaglandin] data....[1]

Defendant Scolnick's reference to the cause of the cardiovascular events being "mechanism based as we worried it was," and his statement that Drs. Oates, Nies and Gertz "were right" about the meaning of the "urine Pg [prostaglandin] data," was an admission that he understood that it was VIOXX's inhibition of

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[1] Unless otherwise stated, all emphases herein are added.

prostacyclin (which was anti-thrombotic), combined with VIOXX's lack of any effect on thromboxane (which was *pro*-thrombotic), that caused patients taking VIOXX to experience a significantly increased risk of serious adverse CV events.

11. On March 27, 2000, Merck issued a press release discussing VIGOR's results. The release emphasized that VIGOR's results showed that VIOXX had a superior GI safety profile than naproxen, while also noting the significantly higher incidence of adverse CV events among VIOXX users compared to naproxen users. However, rather than acknowledge their conclusion that the statistically significant difference in the number of heart attacks and other adverse CV events in the VIGOR trial was "mechanism based" (*i.e.*, attributable to the manner in which VIOXX upset the body's homeostatic balance of prostacyclin and thromboxane) — an admission that the Officer Defendants knew would likely "kill the drug" and precipitate a financial crisis for Merck — the Officer Defendants tried to explain away the difference in VIGOR's adverse CV data by manufacturing a hypothesis that attributed VIGOR's CV results to the alleged "cardioprotective" properties of naproxen (the "naproxen hypothesis"). For example, as Merck's March 27, 2000 press release represented:

> ***[S]ignificantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation***. This effect on these events had not been observed previously in any clinical studies for naproxen. ***VIOXX, like all COX-2***

selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects.

To further support their "naproxen hypothesis," the press release further falsely represented that "[a]n extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with VIOXX, showed no indication of a difference in the incidence of thromboembolic events between VIOXX, placebo and comparator NSAIDs."

12. The VIGOR results were widely reported. Market analysts understood that the higher rate of adverse CV events among VIOXX users in VIGOR could be due to either (a) purported cardioprotective properties of naproxen or (b) the prothrombotic effect of VIOXX. However, in the wake of Merck's repeatedly stated belief that the difference in the rate of adverse CV events between VIOXX and naproxen was likely due to and "consistent with" a cardioprotective effect of naproxen rather than a prothrombotic effect of VIOXX — and in the wake of Merck's further assurances that there was no indication of a difference in the incidence of thromboembolic events between VIOXX, placebo and comparator NSAIDS in Merck's other clinical trial data — virtually all members of the scientific, medical and Wall Street analyst communities either accepted or treated as plausible Merck's publicly stated view that the "naproxen hypothesis" was the "likeliest interpretation" of the VIGOR study results.

13. However, as defendant Scolnick's internal March 9, 2000 email confirms, unbeknownst to investors Merck actually believed that the increased CV events in VIGOR ***were caused by VIOXX,*** and as detailed below

Merck concocted and advanced the "naproxen hypothesis" to protect VIOXX's commercial viability.

14. Over the weeks, months and years following the release of the VIGOR study results, Merck and the Officer Defendants (notably Scolnick and Reicin) continued to promote the "naproxen hypothesis" and to tout VIOXX's purported safety and blockbuster commercial viability, even as additional evidence continued to mount internally at Merck that VIOXX caused heart attacks and other serious adverse CV events.

15. For example, by no later than early April 2000 — just a week after Merck first announced the results of the VIGOR study — the preliminary results of another Merck study (the ADVANTAGE study, which also compared VIOXX to naproxen) became available internally at Merck. In an email to defendant Scolnick, defendant Reicin noted that there were ***seven*** heart attacks in one treatment group compared to only ***one*** in the other group. Although the two groups were still "blinded" at that time, there was little doubt that the former group was the VIOXX group and the latter group was the naproxen group. Moreover, as shown by internal Merck emails produced after the Class Period, in November 2000 defendant Reicin pressured another Merck scientist to change the reported cause of death of at least one of the patients in the ADVANTAGE trial who was taking VIOXX from "heart attack" to "unknown cause of death" so as not to "raise concerns" about VIOXX's CV safety and the validity of Merck's "naproxen hypothesis." Merck's manipulation of the ADVANTAGE data in this fashion was not publicly disclosed until April 2005, after the Class Period.

16. By April 2001, Merck and the Officer Defendants were also in possession of nonpublic information concerning the results of two clinical trials (known as Protocol 078 and Protocol 091) that they had conducted to assess the effects of VIOXX on Alzheimer's disease. On both a standard "intention to treat" basis as well as a standard "on treatment" basis, these studies showed statistically significant increases in deaths (including a statistically significant increase in heart disease deaths) in patients being treated with VIOXX compared to those being treated with placebo — results that obviously would have been material to investors and medical professionals alike.

17. However, Merck chose not to disclose to the public that its internally prepared analyses showed a statistically significant increase in mortality (including a statistically significant increase in heart disease deaths) for VIOXX patients whether using standard "intention-to-treat" or "on treatment" analysis. Instead, Merck attempted to conceal these studies' statistically significant results by creating and then employing a non-standard "On Drug" methodology pursuant to which it reported substantially reduced — and ***not*** statistically significant — increased mortality risks for patients who used VIOXX in these two trials. Merck's concealment of the true nature and extent of the safety risks of VIOXX from the institutional review boards ("IRB's") that were responsible for patient enrollment at the clinical test sites for these trials was sufficiently improper and outrageous that, when the relevant facts were finally disclosed in 2008, the authors of an article published in the *Journal of the American Medical Association ("JAMA")* characterized Merck's extraordinary misconduct as "violating the trust of [the] human participants who volunteered to participate" in the trials.

18. Notwithstanding this growing body of additional, material non-public information in Merck's possession concerning VIOXX's association with increased CV risks and deaths, Merck continued to falsely downplay any concerns about VIOXX's safety or profit potential, and to falsely reaffirm its purported belief in the "naproxen hypothesis." For example, on August 21, 2001 — the day before *JAMA* published an article that expressed concerns about VIOXX's possible prothrombotic effects — a Merck spokesman assured *Bloomberg News* that Merck had "additional data beyond what [the authors of the *JAMA* article] cite, and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo." Approximately six weeks later, on October 9, 2001, *The New York Times* quoted defendant Scolnick reiterating (a) that Merck's belief that the "naproxen hypothesis" remained the "likeliest interpretation" of the VIGOR data, and (b) that Merck had found no evidence in other studies that VIOXX increased the risk of heart attacks. Scolnick added that without the "theoretical question" raised by Dr. FitzGerald's early research concerning VIOXX's impact on prostacyclin "no one would have a question remaining in their mind that there might be an additional interpretation" (*i.e.*, that VIOXX caused increased CV risks). Similarly, in an April 2002 conference call, a Merck spokesman reiterated the Company's "belief that the effects seen in VIGOR were [due to] the anti-platelet effect of naproxen" and that that was "a position that Merck has always had."

19. In the fall of 2003, the results of a Merck-funded study at Brigham and Women's Hospital in Boston (the "Brigham Study") became public. The Brigham Study, which looked at the records of almost 55,000 Medicare patients over the age of 65, found an

increased risk of heart attack in patients taking VIOXX, compared with patients taking Celebrex (a rival COX-2 inhibitor that was VIOXX's main competitor) and with patients not taking any painkiller. The results of the Brigham Study raised doubts about Merck's "naproxen hypothesis," but Merck aggressively countered the results of the study by arguing that epidemiological studies (such as the Brigham study) were not as significant as the results of clinical trials, and by vigorously reiterating its purported belief in the "naproxen hypothesis." As a result of Merck's renewed public defense of its "naproxen hypothesis," investor concerns about VIOXX were substantially assuaged, and the market continued to be materially misled as to Merck's actual beliefs and the true extent to which VIOXX's commercial viability was in jeopardy.

20. On September 30, 2004, Merck announced that it was withdrawing VIOXX from the market based on a new study showing an "increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy." In response to this news, the price of Merck common stock plummeted more than $12 in heavy trading to close at $33.00, down approximately 27% from its closing price the previous day. Securities analysts expressed shock and surprise at the sudden withdrawal of VIOXX. Less than five weeks later, on November 1, 2004 (the last day of the Class Period), *The Wall Street Journal* disclosed that "internal Merck emails and marketing materials as well as interviews with outside scientists show that the company fought forcefully for years to keep safety concerns [from] destroying the drug's commercial prospects." This news prompted one securities analyst to comment that ***"new information indicates to us that the situation might not be as innocent as we thought***.... We recommend

that investors sell Merck shares." In response to these further revelations, Merck's stock price fell a further 9.7%.

21. Since the end of the Class Period in November 2004, and as noted above and as further described below, significant information that was previously unknown to and/or concealed from Plaintiffs and investors has been obtained by Lead Counsel which details Merck's and the Officer Defendants' knowing concealment and manipulation of VIOXX trial data, their lack of good faith belief in the Company's "naproxen hypothesis," their efforts to intimidate and discredit anyone who attempted to seriously challenge VIOXX's safety, and their knowingly (or at least recklessly) materially false and misleading public assurances throughout the Class Period that there was "no indication" that VIOXX caused adverse CV events, and that VIOXX would continue to generate billions of dollars in annual sales for Merck for years to come. By this Complaint, Plaintiffs, on behalf of themselves and the other members of the Class, seek a recovery for the massive financial losses that they and their fellow Class members have suffered as a result of Defendants' violations of the federal securities laws, as further set forth herein.

* * * * *

23. This Complaint also sets forth separately certain non-fraud claims under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 (the "Securities Act") 15 U.S.C. §§ 77k, 77l(a)(2) and 77o against Merck and those individual defendants who are named as "Securities Act Defendants" in ¶ 56 below. Plaintiffs' Securities Act claims are not based on any knowing or reckless misconduct on the part of the Securities Act Defendants,

and such claims do not allege fraud, do not sound in fraud and expressly disavow any fraud-related allegation set forth herein and instead are premised on the fact that Merck's Registration Statement dated April 26, 2002 (the "2002 Registration Statement"), the prospectus dated April 30, 2002 (the "April 2002 Prospectus"), and the prospectus dated June 10, 2004 (the "June 2004 Prospectus") for the Merck Stock Investment Plan ("MSIP") contained material misrepresentations and omissions (without regard to any defendant's state of mind) related to VIOXX.

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MERCK **News Release**

FOR IMMEDIATE RELEASE

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Merck Informs Investigators of Preliminary Results Of Gastrointestinal Outcomes Study with VIOXX(R)

WEST POINT, Pa., March 27, 2000 — Merck & Co., Inc. (NYSE: MRK) today informed its investigators of a preliminary analysis from a large gastrointestinal (GI) outcomes study that compared **Vioxx**(R) (rofecoxib) with naproxen in patients with rheumatoid arthritis. Among patients treated with Vioxx, there was a significantly reduced incidence of serious gastrointestinal events compared to patients treated with naproxen. Merck plans to submit the information to the U.S. Food and Drug Administration (FDA) and other regulatory agencies worldwide in the next few months.

In addition, significantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation. This effect on these events had not been observed previously in any clinical studies for naproxen. Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects. As a result, Merck is notifying investigators, who are conducting other Merck studies with **Vioxx** or another

investigational medicine in the same class, of protocol amendments to allow the addition of low-dose aspirin where appropriate. Patients using low-dose aspirin, which also blocks platelet aggregation, were excluded from the GI outcomes study. Vioxx does not interfere with the ability of low-dose aspirin to block platelet aggregation.

The completed study, called VIGOR (Vioxx Gastrointestinal Outcomes Research), compared the GI safety of Vioxx (50 mg once daily) to prescription-strength naproxen (500 mg twice a day) in approximately 8,000 patients with rheumatoid arthritis. The study specifically assessed the incidence of certain types of clinically significant upper GI events, including perforations, ulcers, obstructions and bleeds. Naproxen is a commonly used non-steroidal anti-inflammatory drug (NSAID) indicated for the treatment of a number of arthritic diseases, including rheumatoid arthritis. Vioxx is not approved for the treatment of rheumatoid arthritis, nor is an application for this use under review. Vioxx is approved in the U.S. for the relief of the signs and symptoms of osteoarthritis, management of acute pain in adults and treatment of menstrual pain.

Researchers believe that NSAIDs work by inhibiting two related enzymes: COX-1, the enzyme that helps maintain the stomach lining and promotes platelet aggregation, and COX-2, the enzyme that triggers pain and inflammation. At therapeutic doses, **Vioxx** works by selectively inhibiting COX-2 without inhibiting COX-1; non-selective NSAIDs like naproxen inhibit both COX-1 and COX-2. Medicines like aspirin and naproxen that significantly inhibit COX-1 block platelet aggregation and therefore have the potential to provide cardioprotection.

An extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with **Vioxx,** showed no indication of a difference in the incidence of thromboembolic events between **Vioxx,** placebo and comparator NSAIDs.

Further analyses are ongoing, and final results of the GI outcomes study with **Vioxx** will be presented at peer-reviewed medical meetings this year.

Important information about Vioxx

The recommended dose of Vioxx for the treatment of osteoarthritis is 12.5 mg once daily. Some patients may receive additional benefit by increasing the dose to 25 mg once daily.

Serious stomach problems, such as bleeding, can occur without warning symptoms. Administration of low-dose aspirin with Vioxx may result in an increased rate of GI ulcers or other complications compared to use of **Vioxx** alone. Physicians and patients should remain alert for signs and symptoms of gastrointestinal bleeding.

Common side effects reported in osteoarthritis clinical trials with Vioxx were upper-respiratory infection, diarrhea, nausea and high blood pressure. People who have had an allergic reaction to Vioxx, aspirin or other NSAIDs should not take Vioxx. Safety and effectiveness in children below the age of 18 have not been studied.

Merck & Co., Inc. is a global, research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of human and animal health products, directly and through its joint

ventures, and provides pharmaceutical benefit services through Merck-Medco Managed Care.

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Full prescribing information for **Vioxx**(R) follows, and is also available by calling 1-800-753-0352, ext. 726.

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COMPARISON OF UPPER GASTROINTESTINAL TOXICITY OF ROFECOXIB AND NAPROXEN IN PATIENTS WITH RHEUMATOID ARTHRITIS

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ABSTRACT

Background: Each year, clinical upper gastrointestinal events occur in 2 to 4 percent of patients

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who are taking nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). We assessed whether rofecoxib, a selective inhibitor of cyclooxygenase-2, would be associated with a lower incidence of clinically important upper gastrointestinal events than is the nonselective NSAID naproxen among patients with rheumatoid arthritis.

Methods: We randomly assigned 8076 patients who were at least 50 years of age (or at least 40 years of age and receiving long-term glucocorticoid therapy) and who had rheumatoid arthritis to receive either 50 mg of rofecoxib daily or 500 mg of naproxen twice daily. The primary end point was confirmed clinical upper gastrointestinal events (gastroduodenal perforation or obstruction, upper gastrointestinal bleeding, and symptomatic gastroduodenal ulcers).

Results: Rofecoxib and naproxen had similar efficacy against rheumatoid arthritis. During a median follow-up of 9.0 months, 2.1 confirmed gastrointestinal events per 100 patient-years occurred with rofecoxib, as compared with 4.5 per 100 patient-years with naproxen (relative risk, 0.5; 95 percent confidence interval, 0.3 to 0.6; $P<0.001$). The respective rates of complicated confirmed events (perforation, obstruction, and severe upper gastrointestinal bleeding) were 0.6 per 100 patient-years and 1.4 per 100 patient-years (relative risk, 0.4; 95 percent confidence interval, 0.2 to 0.8; $P=0.005$). The incidence of myocardial infarction was lower among patients in the naproxen group than among those in the rofecoxib group (0.1 percent vs. 0.4 percent; relative risk, 0.2; 95 percent confidence interval, 0.1 to 0.7); the overall mortality rate and the rate of death from cardiovascular causes were similar in the two groups.

Conclusions: In patients with rheumatoid arthritis, treatment with rofecoxib, a selective inhibitor of cyclooxygenase-2, is associated with significantly fewer clinically important upper gastrointestinal events than treatment with naproxen, a nonselective inhibitor. (N Engl J Med 2000;343:1520-8.)

Nonsteroidal antiinflammatory drugs (NSAIDs) are among the most commonly used medications in the world.[1] A major factor limiting their use is gastrointestinal toxicity. Although endoscopic studies reveal that gastric or duodenal ulcers develop in 15 to 30 percent of patients who regularly take NSAIDs,[2] the chief concern is clinically important gastrointestinal problems, such as bleeding. It has been estimated that more than 100,000 patients are hospitalized and 16,500 die each year in the United States as a result of NSAID-associated gastrointestinal events.[3,4]

Most NSAIDs inhibit both cyclooxygenase-1 and cyclooxygenase-2, isoenzymes involved in the synthesis of prostaglandins.[5] Cyclooxygenase-1 is constitutively expressed and generates prostanoids involved in the maintenance of the integrity of gastrointestinal mucosa and platelet aggregation,[6] whereas at sites of inflammation, cyclooxygenase-2 is induced to generate prostaglandins that mediate inflammation and pain.[7] The antiinflammatory effects of nonselective NSAIDs (those that inhibit both cyclooxygenase-1 and cyclooxygenase-2) therefore appear to be mediated through the inhibition of cyclooxygenase-2,[8] whereas their harmful effects in the gastrointestinal tract as well as their antiplatelet effects are believed to occur primarily through the inhibition of cyclooxygenase-1.[5]

Agents that selectively inhibit cyclooxygenase-2 have antiinflammatory and analgesic effects that are similar

to those of nonselective NSAIDs,[9 10 11 12] but they induced significantly fewer ulcers in endoscopic trials.[12 13 14 15] Whether such a decrease in the number of ulcers translates into a similar decrease in the number of clinical gastrointestinal events is a matter of controversy. We performed a prospective, randomized, double-blind comparison of rofecoxib and naproxen in more than 8000 patients with rheumatoid arthritis.

METHODS

Study Population

Patients with rheumatoid arthritis who were at least 50 years old (or at least 40 years old and receiving long-term glucocorticoid therapy) and who were expected to require NSAIDs for at least one year were eligible. Patients were excluded if they had a history of another type of inflammatory arthritis, upper gastrointestinal surgery, or inflammatory bowel disease; an estimated creatinine clearance of 30 ml or less per minute; a positive test for fecal occult blood (this test was performed at base line in all patients); an unstable medical condition; a history of cancer or alcohol or drug abuse in the five years before the study; a history of cerebrovascular events in the two years before the study; or a history of myocardial infarction or coronary bypass in the year before the study. Patients with morbid obesity and those who required or who had been receiving treatment with aspirin, ticlopidine, anticoagulants, cyclosporine, misoprostol, sucralfate, or proton-pump inhibitors or treatment with histamine H(sub 2)-receptor antagonists in prescription-strength doses were also excluded from the study. Patients enrolled in the study were not thought to require the use of these agents by their treating physicians.

Study Design

The study was conducted at 301 centers in 22 countries. Three to 14 days after discontinuing NSAIDs, eligible patients were randomly assigned to receive either 50 mg of rofecoxib (Vioxx, Merck, Whitehouse Station, N.J.) once daily or 500 mg of naproxen (Novopharm Biotech, Toronto) twice daily. The groups were stratified according to the presence or absence of a history of gastroduodenal ulcer, upper gastrointestinal bleeding, and gastroduodenal perforation. Blinding was achieved through the use of a matching placebo for each study medication.

Patients were permitted to take acetaminophen, non-NSAID analgesic medications, glucocorticoids, and disease-modifying drugs (e.g., methotrexate) to control their rheumatoid arthritis. Patients were also allowed to take antacids and H(sub 2)-receptor antagonists in the following maximal doses: ranitidine, 150 mg daily; famotidine, 20 mg daily; cimetidine, 400 mg daily; and nizatidine, 150 mg daily. Nonstudy NSAIDs were not allowed. After randomization, the patients returned to the clinic at six weeks and at four months and every four months thereafter until the end of the study. Patients were contacted by telephone at week 10 and every four months thereafter. Compliance was assessed by pill counts at clinic visits and by questioning of patients during the scheduled telephone calls. Serum was obtained from all patients for Helicobacter pylori testing (HM-CAP, Enteric Products, Stonybrook, N.Y.). Investigators were not informed of the results of these tests during the study.

The institutional review board or ethics review committee at each center approved the protocol, and all patients gave written informed consent. A steering

committee oversaw the study design, conduct of the trial, analyses of data, and drafting of this report. This committee was composed of 14 members, 2 of whom were employees of the sponsoring pharmaceutical company. An independent data and safety monitoring board monitored the patients' safety. An independent, external (end-point) committee whose members were unaware of the patients' treatment assignments reviewed the data to determine which patients had reached the study end points. Because highly selective cyclooxygenase-2 inhibitors do not inhibit platelet aggregation, which is mediated by cyclooxygenase-1, there was a possibility that the incidence of thrombotic cardiovascular events would be lower among patients treated with nonselective cyclooxygenase inhibitors than among those treated with cyclooxygenase-2-selective inhibitors. Therefore, cardiovascular events were also assessed for a future meta-analysis by independent committees whose members were unaware of the patients' treatment assignments. A separate analysis of these events, however, was not specified in the study design.

Study End Points

Patients who had potential clinical upper gastrointestinal events were evaluated and treated according to the standard practice of the physicians who were caring for them. Patients who stopped taking the study medication before the study ended were followed until the end of the study to determine whether an upper gastrointestinal event had occurred. Only events that were confirmed by the end-point committee according to prespecified criteria and that occurred during treatment or within 14 days after the discontinuation of treatment

were included in the primary analysis. (Table 1: Criteria for Gastrointestinal Events has been omitted.)

In addition, the protocol called for the analysis of all episodes of gastrointestinal bleeding, including confirmed and unconfirmed episodes of upper gastrointestinal bleeding, and bleeding from a site beyond the duodenum that resulted in hospitalization, discontinuation of treatment, or a decrease in the hemoglobin level of at least 2 g per deciliter.

Assessment of Efficacy

For each patient both the investigator and the patient answered a Global Assessment of Disease Activity question at base line (after the discontinuation of prestudy NSAIDs), 6 weeks, 4 months, and 12 months and at the end of the study or when treatment was discontinued. The score can range from 0 ("very well") to 4 ("very poor"), and higher scores indicate more disease activity. The Modified Health Assessment questionnaire was administered only to patients enrolled at centers in the United States at base line, at six weeks, and at the end of the study or when treatment was discontinued. This questionnaire evaluates the extent of functional disability in eight types of tasks performed on a daily basis. The level of effort required to perform each task is assessed on a 4-point scale on which a score of 0 indicates no difficulty in performing the task and a score of 3 indicates an inability to perform the task.[16] Higher scores indicate more severe disability.

Statistical Analysis

The primary hypothesis was that the risk of confirmed upper gastrointestinal events (gastroduodenal perforation or obstruction, upper gastrointestinal bleeding, and symptomatic gastroduodenal ulcers) would be lower among patients who were taking rofecoxib than

among those who were taking naproxen. Secondary hypotheses were that the risk of confirmed complicated events (perforation, obstruction, and severe upper gastrointestinal bleeding) and the risk of both confirmed and unconfirmed upper gastrointestinal events would be lower among patients who were taking rofecoxib.

Cox proportional-hazards analysis was used to compare the effect of treatment; the presence or absence of a history of gastrointestinal events was a stratification factor in the analysis.[17 18] The scores for the Global Assessment of Disease Activity question and Modified Health Assessment questionnaire were analyzed in terms of the mean change from base line during the treatment period. The primary population for analysis comprised all randomized patients. Subgroup analyses were conducted with use of Cox regression analysis.[17 18] Interactions between treatments and subgroups were assessed to determine whether the effect of rofecoxib as compared with that of naproxen was consistent in the subgroups. We assessed data on general safety by evaluating 95 percent confidence intervals of the differences in the proportions of the treatment groups with each adverse event.[19] All statistical tests were two-sided.

RESULTS

Characteristics of the Patients

Between January 1999 and July 1999, we screened 9539 patients and enrolled 8076; 4047 were randomly assigned to receive rofecoxib, and 4029 to receive naproxen. The major reasons for exclusion were a contraindication to prolonged NSAID therapy (in the case of 246 patients), a positive test for fecal occult blood

(203 patients), and a failure to meet inclusion criteria (355 patients). The median follow-up was 9.0 months in both treatment groups (range, 0.5 to 13). A total of 5742 patients (71.1 percent) continued to take their assigned medication until the end of the study. Rates of discontinuation were similar in the two groups: 29.3 percent in the rofecoxib group (16.4 percent because of adverse events, 6.3 percent because of a lack of efficacy, and 6.6 percent for other reasons) and 28.5 percent in the naproxen group (16.1 percent because of adverse events, 6.5 percent because of a lack of efficacy, and 5.9 percent for other reasons). Ninety-nine percent of the patients in both groups took their medication on at least 75 percent of the study days. The base-line characteristics were similar in the two groups (Table 2: Base-Line Characteristics of the Patients has been omitted.)

Efficacy

Rofecoxib and naproxen had similar efficacy against rheumatoid arthritis (Table 3). In addition, the rates of discontinuation of treatment owing to a lack of efficacy were low in both groups (6.3 percent in the rofecoxib group and 6.5 percent in the naproxen group). (Table 3: Effectiveness of Rofecoxir and Naproxen for Rheumatoid Arthritis has been omitted.)

Adverse Gastrointestinal Events

Confirmed upper gastrointestinal events occurred in 177 patients. In 53 of these patients the event was complicated. An additional 13 patients had events that were reported by investigators but that were judged by the end-point committee to be unconfirmed.

The time to the development of a confirmed upper gastrointestinal event is shown in Figure 1. (Figure 1: Cumulative incidence of the Primary End Point of a Confirmed Upper Gastrointestinal Event among All

Randomized Patients has been omitted.) The rates per 100 patient-years and incidences of the prespecified clinical events are shown in Tables 4 and 5, respectively. (Table 4: Incidence of Gastrointestinal Events in the Treatment Groups and Table 5: Incidence of Confirmed Upper Gastrointestinal Events have been omitted.) The relative risk of confirmed upper gastrointestinal events for patients in the rofecoxib group as compared with those in the naproxen group was 0.5 (95 percent confidence interval, 0.3 to 0.6; $P<0.001$), whereas the relative risk of complicated confirmed upper gastrointestinal events was 0.4 (95 percent confidence interval, 0.2 to 0.8; $P=0.005$). The relative risk of complicated upper gastrointestinal bleeding for patients in the rofecoxib group as compared with those in the naproxen group was 0.4 (95 percent confidence interval, 0.2 to 0.7; $P=0.004$), whereas the relative risk of bleeding beyond the duodenum was 0.5 (95 percent confidence interval, 0.2 to 0.9; $P=0.03$).

A per-protocol analysis of the 7925 patients without substantial protocol violations demonstrated relative risks of confirmed upper gastrointestinal events and complicated confirmed events of 0.4 (95 percent confidence interval, 0.3 to 0.6; $P<0.001$) and 0.4 (95 percent confidence interval, 0.2 to 0.7; $P=0.003$), respectively. The results of an intention-to-treat analysis of all confirmed upper gastrointestinal events throughout the study, including those that occurred at any time after the discontinuation of treatment, were similar and remained statistically significant (data not shown).

Subgroup analyses showed the following relative risks of clinical gastrointestinal events among the patients in the rofecoxib group as compared with those

in the naproxen group: patients with no prior gastrointestinal events (relative risk, 0.5; 95 percent confidence interval, 0.3 to 0.7), patients with prior gastrointestinal events (relative risk, 0.4; 95 percent confidence interval, 0.2 to 0.8), patients with no glucocorticoid therapy at base line (relative risk, 0.7; 95 percent confidence interval, 0.4 to 1.2), and patients with glucocorticoid therapy at base line (relative risk, 0.4; 95 percent confidence interval, 0.2 to 0.6). The relative risks in these subgroups and the other prespecified subgroups (defined according to sex, race or ethnic group, and location of study center) were not significantly different, indicating that there was no significant interaction between the treatments and the subgroups.

Treatment with rofecoxib was associated with a significantly lower incidence of clinical gastrointestinal events regardless of the results of serologic tests for H. pylori. However, the relative risks of clinical events among H. pylori-negative patients and H. pylori-positive patients were significantly different (P=0.04, data not shown). Finally, the relative risk of gastrointestinal events remained significantly lower (0.1; 95 percent confidence interval, 0.02 to 1.0) in the rofecoxib group than in the naproxen group even in a subgroup at very low risk (i.e., patients who were younger than 65 years, who were negative for H. pylori, who had no history of a clinical gastrointestinal event, and who were not taking glucocorticoids at base line).

General Safety

The safety of both rofecoxib and naproxen was similar to that reported in previous studies.[20] [21] The mortality rate was 0.5 percent in the rofecoxib group and 0.4 percent in the naproxen group. The rate of death from cardiovascular causes was 0.2 percent in both

groups. Ischemic cerebrovascular events occurred in 0.2 percent of the patients in each group. Myocardial infarctions were less common in the naproxen group than in the rofecoxib group (0.1 percent vs. 0.4 percent; 95 percent confidence interval for the difference, 0.1 to 0.6 percent; relative risk, 0.2; 95 percent confidence interval, 0.1 to 0.7). Four percent of the study subjects met the criteria of the Food and Drug Administration (FDA) for the use of aspirin for secondary cardiovascular prophylaxis (presence of a history of myocardial infarction, angina, cerebrovascular accident, transient ischemic attack, angioplasty, or coronary bypass)22 but were not taking low-dose aspirin therapy. These patients accounted for 38 percent of the patients in the study who had myocardial infarctions. In the other patients the difference in the rate of myocardial infarction between groups was not significant (0.2 percent in the rofecoxib group and 0.1 percent in the naproxen group). When the data showing a reduction in the rate of myocardial infarction in the naproxen group became available after the completion of this trial, Merck, the manufacturer of rofecoxib, notified all investigators in ongoing studies of a change in the exclusion criteria to allow patients to use low-dose aspirin. There was no association between hypertension and myocardial infarction; only a single patient (in the rofecoxib group) had both hypertension and a myocardial infarction as adverse events.

The most common adverse events leading to discontinuation of treatment, excluding the gastrointestinal end points, were dyspepsia, abdominal pain, epigastric discomfort, nausea, and heartburn. In the rofecoxib group, significantly fewer patients discontinued treatment as a result of any one of these five upper gastrointestinal symptoms than in the

naproxen group (3.5 percent vs. 4.9 percent). The rates of discontinuation for any gastrointestinal events, including gastrointestinal end points, were also significantly lower in the rofecoxib group than in the naproxen group (7.8 percent vs. 10.6 percent). The incidence of adverse effects related to renal function was low and was similar in the two groups (1.2 percent in the rofecoxib group and 0.9 percent in the naproxen group); only 0.2 percent of patients in each group discontinued treatment because of these adverse effects.

DISCUSSION

We found that, in patients with rheumatoid arthritis, treatment with rofecoxib at twice the maximal dose approved by the FDA for long-term use resulted in significantly lower rates of clinically important upper gastrointestinal events and complicated upper gastrointestinal events than did treatment with a standard dose (1000 mg per day) of naproxen. We also found that the incidence of complicated upper gastrointestinal bleeding and bleeding from beyond the duodenum was significantly lower among patients who received rofecoxib. Only 41 patients would need to be treated with rofecoxib rather than naproxen to avert one clinical upper gastrointestinal event in a one-year period. Although the optimal dose of rofecoxib for the treatment of rheumatoid arthritis has yet to be determined, data from a prior study indicate that maximal efficacy is achieved at a daily dose of 25 mg.[23]

A prospective study that compared NSAIDs alone with NSAIDs plus misoprostol reported that 0.95 percent of patients with rheumatoid arthritis who were taking an NSAID alone had upper gastrointestinal

complications over a period of six months,[24] with a relative reduction in the risk of such complications with combination treatment of 40 percent during this period. These results are similar to our finding of a cumulative incidence of serious upper gastrointestinal events over a six-month period of 0.75 percent in the naproxen group and a relative reduction in risk of 67 percent in the rofecoxib group (data not shown). A 50 percent reduction in the incidence of clinically important upper gastrointestinal events with rofecoxib as compared with a nonselective NSAID was also found in a prespecified combined analysis of eight double-blind studies that included 4921 patients with osteoarthritis, none of whom received glucocorticoids.[25] Patients with rheumatoid arthritis have a higher risk of upper gastrointestinal events than do patients with osteoarthritis.[4] Thus, the results of our study extend the results of the combined analysis to a group of patients at higher risk of bleeding.

The results of a randomized, double-blind comparison of the cyclooxygenase-2-selective inhibitor celecoxib and the nonselective NSAIDs ibuprofen and diclofenac were recently published.[26] In this trial of 7968 patients, 73 percent of whom had osteoarthritis and 27 percent of whom had rheumatoid arthritis, data were reported from the first 6 months of a study period that extended for up to 13 months. Treatment with celecoxib was associated with a nonsignificant ($P=0.09$) trend toward a decrease in the incidence of the primary end point (complicated ulcers and erosions) and a significant decrease ($P=0.02$) in the incidence of the secondary end point (complicated and symptomatic ulcers).

The incidence of clinically important gastrointestinal events was lower in the rofecoxib group than in the naproxen group in all subgroups we examined.

Concomitant glucocorticoid and NSAID therapy has been reported to be associated with a higher risk of a clinical gastrointestinal event than is NSAID therapy alone.[4] Therefore, a larger reduction in the incidence of events might have been expected in the subgroup that received both an NSAID and glucocorticoids. There was a greater reduction in the relative risk of events in the subgroup of patients who were taking glucocorticoids at base line than in the subgroup of patients who were not taking glucocorticoids at base line, but the difference between the groups was not significant.

Whether ulcers identified by endoscopic examination are markers of a clinical gastrointestinal event has been a matter of controversy. The relative reduction in the risk of such ulcers in two identical studies that compared 50 mg of rofecoxib daily with 800 mg of ibuprofen three times a day was 71 percent at six months.[13,14] Thus, our findings support the concept that the results of endoscopic studies of ulcers can be extrapolated to clinical gastrointestinal events.

In prior endoscopic studies, the frequency of ulcers was similar in patients taking rofecoxib and those taking placebo.[13,14] We could not include a placebo group, and no studies have yet assessed whether a cyclooxygenase-2-selective inhibitor or the combination of nonselective NSAIDs plus gastroprotective drugs (such as misoprostol and proton-pump inhibitors) will achieve similar results.

Gastrointestinal symptoms are extremely common with NSAID therapy, as demonstrated by the fact that, in our study, the five most common adverse events leading to the discontinuation of treatment were upper gastrointestinal symptoms. Although gastrointestinal symptoms are poorly correlated with endoscopic findings

of ulcers or clinical gastrointestinal events,[27] significantly fewer patients in the rofecoxib group than in the naproxen group discontinued treatment because of gastrointestinal symptoms.

The overall mortality rate was similar in the two groups, as were the rates of death from gastrointestinal events and from cardiovascular causes. The rate of myocardial infarction was significantly lower in the naproxen group than in the rofecoxib group (0.1 percent vs. 0.4 percent). This difference was primarily accounted for by the high rate of myocardial infarction among the 4 percent of the study population with the highest risk of a myocardial infarction, for whom low-dose aspirin is indicated.22 The difference in the rates of myocardial infarction between the rofecoxib and naproxen groups was not significant among the patients without indications for aspirin therapy as secondary prophylaxis.

Naproxen inhibits the production of thromboxane by 95 percent and inhibits platelet aggregation by 88 percent, and this effect is maintained throughout the dosing interval;[28] therefore, the effects of regular use of naproxen may be similar to those of aspirin. Flurbiprofen, another NSAID that is a potent inhibitor of platelet-derived thromboxane, led to a 70 percent reduction in the rate of reinfarction as compared with placebo among patients in whom acute myocardial infarction was successfully treated with thrombolysis, angioplasty, or both.[29]

Analyses of 7535 patients in double-blind trials comparing rofecoxib with placebo and other NSAIDs (diclofenac, ibuprofen, and nabumetone) that do not produce sustained, maximal inhibition of platelet aggregation revealed similar rates of myocardial infarction in all groups[30] (and unpublished data). Thus,

our results are consistent with the theory that naproxen has a coronary protective effect and highlight the fact that rofecoxib does not provide this type of protection owing to its selective inhibition of cyclooxygenase-2 at its therapeutic dose and at higher doses. The finding that naproxen therapy was associated with a lower rate of myocardial infarction needs further confirmation in larger studies.

In summary, the use of the cyclooxygenase-2-selective inhibitor rofecoxib resulted in significantly fewer clinically important upper gastrointestinal events than did treatment with naproxen, a nonselective NSAID. The two drugs had similar rates of clinical effectiveness.

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Editor's note: Our policy requires authors of Original Articles to disclose all financial ties with companies that make the products under study or competing products. In this case, the large number of authors and their varied and extensive financial associations with relevant companies make a detailed listing here impractical. Readers should know, however, that 11 of the 13 principal authors (C.B., L.L., R.B.-V., B.D., R.D., M.B.F., C.J.H., M.C.H., T.K.K., T.J.S., A.W.) have had financial associations with Merck — which sponsored the study — and, in most cases, with many other companies. The associations include consultancies, receipt of research grants and honorariums, and participation on advisory boards. The other two principal authors (A.R., D.S.) are employees of Merck. Details are included as part of the article on the Journal's Web site (http://www.nejm.org).

APPENDIX

The following persons participated in the study: International Steering Committee: C. Bombardier (chair), L. Laine (cochair), A. Reicin, M. Hochberg, R. Day, T. Capizzi, P. Brooks, R. Burgos-Vargas, B. Davis, M. Ferraz, C. Hawkey, T.K. Kvien, T. Schnitzer, A. Weaver; Data Safety Board: M. Weinblatt (chair); D. Bjorkman, J. Neaton, A. Silman, R. Sturrock; End-Point Adjudication Committee: M. Griffin (chair), D. Jensen, M. Langman; Investigators: Argentina: E. DiGiorgio, H. Laborde, O. Messina, A. Strusberg; Australia: J. Bertouch, R. Day, G. McColl, P. Ryan, S. Sharma; Brazil: R. Bonfiglioli, C. Borges, J. Brenol, N. da Silva, M. Ferraz, F. Lima, C. Moreira, G. Novaes, A. Pessoa, F. Petean, S. Radominski, A. Samara, B. Souza; Canada: T. Anastassiades, M. Atkinson, A. Beaulieu, M. Bell, M. Camerlain, J. Canvin, M. Cohen, J. Hanly, J. Karsh, T. McCarthy, W. Olszynski, P. Patel, Y. Pesant, W. Pruzanski, K. Siminovitch, J. Thome, V. Verdejo-Aguilar; Chile: L. Barria, C. Fuentealba, L. Massardo, P. Riedemann, L. Roca, H. Rossi; China (Hong Kong): C. Lau; Colombia: M. Abello, P. Chalem, M. Jannault, J. Molina; Costa Rica: R. Alpizar, H. Garcia-Sancho;

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RISK OF CARDIOVASCULAR EVENTS ASSOCIATED WITH SELECTIVE COX-2 INHIBITORS

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ASPIRIN AND NONSTEROIDAL anti-inflammatory agents (NSAIDs) have proven analgesic, anti-inflammatory, and antithrombotic properties but also have significant gastric toxicity. The gastrointestinal toxicity appears to be related to cyclooxygenase 1 (COX-1) inhibition.[1] In 1990, Fu et al[2] detected a novelCOXprotein in monocytes stimulated by interleukin, and a year later Kujubu et al[3] identified a gene with considerable homology to COX-1.

Identification of this COX-2 protein rekindled the efforts of the pharmaceutical industry to produce a safer analgesic and anti-inflammatory drug via selective inhibition of COX-2, and this class of agents was introduced in 1999. By October 2000, celecoxib and rofecoxib had sales exceeding $3 billion in the United States, and a prescription volume in excess of 100 million for the 12- month period ending in July 2000.[4]

The development of COX-2 inhibitors as anti-inflammatory agents without gastric toxicity is based on the premise that COX-1 predominates in the gastric mucosa and yields protective prostaglandins, whereas COX-2 is induced in inflammation and leads to pain, swelling, and discomfort. However, selective COX-2 inhibitors decrease vascular prostacyclin (PGI2)

production and may affect the balance between prothrombotic and antithrombotic eicosanoids.[5] Unlike the platelet inhibition afforded by COX-1 inhibitors, COX-2 inhibitors do not share this salutary antithrombotic property. In contrast, by decreasing vasodilatory and antiaggregatory PGI2 production, COX-2 antagonists may tip the balance in favor of prothrombotic eicosanoids (e.g., thromboxane A2) and may lead to increased cardiovascular thrombotic events.[6] However, atherosclerosis is a process with inflammatory features[7] and selective COX-2 inhibitors may potentially have antiatherogenic effects by virtue of inhibiting inflammation. Herein, we analyze the randomized trials that have been performed to determine whether COX-2 inhibitors are associated with a protective or hazardous effect on the risk of cardiovascular events.

METHODS

We used MEDLINE to identify all published, English-language, randomized, double-blind trials of COX-2 inhibitors from January 1998 to February 2001. Keywords used for our search included *COX-2*, *cyclooxygenase*, *rofecoxib*, and *celecoxib*. We also searched the World Wide Web using the same keywords. A number of studies[8-17] focused only on the gastrointestinal effects of COX-2 inhibitors and did not assess cardiovascular events, most likely because investigators were unaware of any cardiovascular adverse effects at that time. These studies were not included in our analysis because there was no reporting of cardiovascular adverse effects.

COX-2 inhibitors were approved in 1998 and there have been 2 major postmarketing multicenter trials with

these agents. These include the Vioxx Gastrointestinal Outcomes Research study (VIGOR)[18] and the Celecoxib Arthritis Safety Study (CLASS).[19] We also reviewed cardiovascular event rates from Study 085 and Study 090, both submitted to the US Food and Drug Administration (FDA).[20] Table 1 summarizes the design of these trials. (Table 1: Trials of Cyclooxygenase Inhibitors has been omitted.) We also compared the annualized myocardial infarction (MI) rates in the placebo group of a recent meta-analysis of 4 aspirin primary prevention trials with MI rates in the VIGOR and CLASS trials.

An October 12, 2000, Adverse Events Reporting System search limited to the United States was conducted for rofecoxib and celecoxib using the following MedDRA terms: *central nervous system hemorrhages and cerebral accidents*, *coronary artery occlusion*, *coronary artery embolism*, *myocardial infarction*, *gastrointestinal arterial occlusion and infarction*, and *embolism, thrombosis, and stenosis*.[21]

Time-to-event analysis of cardiovascular events was performed based on Kaplan-Meier estimates of cumulative event incidences. The relative risk (RR) of rofecoxib with respect to naproxen was derived from an unstratified Cox model in which the number of events was at least 11; otherwise, RR is the ratio of rates and the P value was calculated from a discrete log-rank distribution. Event rates in the CLASS trial were expressed as percentages of patients, with end points. Frequency of MIs across the trials was compared using the Fisher exact test. Statistical analysis was performed using Statistica version 5.5 (StatSoft Inc, Tulsa, Okla).

RESULTS

VIGOR Trial

The VIGOR trial[18] was a double-blind, randomized, stratified, parallel group trial of 8076 patients comparing the occurrence of gastrointestinal toxicity with rofecoxib (50 mg/d) or naproxen (1000 mg/d) during long-term treatment for patients with rheumatoid arthritis. Aspirin use was not permitted in the study. Although not fully published, cardiovascular event data from the VIGOR trial sponsor was recently submitted to the FDA.[22] The baseline characteristics between the treatment groups in the VIGOR trial demonstrated no meaningful or significant differences. Patients requiring aspirin for cardiac reasons were excluded from this trial.

Based on excessive cardiovascular adverse effects in one group in an interim analysis, the data and safety monitoring board recommended blinded adjudication of cardiovascular events.[22] Ninety-eight cases (65/4047 from the rofecoxib group, 33/4029 from the naproxen group) were sent for adjudication of vascular events. Of these, 45 patients (46 events) in the rofecoxib group and 20 patients (20 events) in the naproxen group were adjudicated to have serious thrombotic cardiovascular adverse events (MI, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks). Event-free survival analysis of these 66 patients showed that the RR (95% confidence interval [CI]) of developing a cardiovascular event in the rofecoxib treatment group was 2.38 (1.39-4.00), P,.001[22] (Figure 1: Time to Cardiovascular Adverse Event in the VIGOR Trial has been omitted.)

A subgroup analysis was performed for patients classified as either "aspirin indicated" or "aspirin not indicated." In the VIGOR trial, aspirinindicated patients were defined as those with past medical history of stroke, transient ischemic attack, MI, unstable angina, angina pectoris, coronary artery bypass graft surgery, or percutaneous coronary interventions. Only 321 (3.9%) patients were aspirinindicated patients (170 in the rofecoxib group; 151 in the naproxen group), because the need for aspirin was an exclusion criterion. The RR of developing serious cardiovascular events among aspirin-indicated patients between the rofecoxib group and the naproxen group was 4.89 (95% CI, 1.41-16.88), $P=.01$, and the RR for as-pirin not indicated patients was 1.89 (95% CI, 1.03-3.45), $P=.04$.[22] Of note, no patient in the aspirin indicated group sustained an MI.

If all cardiovascular events from the adverse event data sets that were termed "serious" in the FDA medical reviewer's opinion were compared, there were 111 patients in the rofecoxib group and 50 patients in the naproxen group with serious cardiovascular events. Eventfree survival analysis showed the risk of serious cardiovascular events in the rofecoxib group was 2.2 times higher (95% CI, 1.62-3.21; $P<.001$) than in the naproxen group.[22]

CLASS Trial

CLASS was a double-blind, randomized controlled trial in which 8059 patients were randomized to receive 400 mg of celecoxib twice per day, 800 mg of ibuprofen 3 times per day, or 75 mg of diclofenac twice per day.[19] Aspirin use (.325 mg/d) was permitted in this study. Although not published, cardiovascular event data from the CLASS study submitted to the FDA were included

in our review.[23] The CLASS trial with celecoxib demonstrated no significant difference in cardiovascular events compared with the NSAIDs. Figure 2 shows the thrombotic event rates in the CLASS trial. (Figure 2: Incidence of MI, Stroke, and Death in the CLASS Trial, Stratified by Aspirin Use has been omitted.) The event rates are stratified by patients receiving aspirin and those not receiving aspirin.

Study 085 and Study 090

Study 085 (N=1042) was a randomized, double-blind, parallel-group, placebo- controlled trial of the efficacy and safety of rofecoxib (12.5 mg/d) vs nabumetone (1000 mg/d) vs placebo after 6 weeks of treatment for osteoarthritis of the knee. Patients were allowed to take low-dose aspirin for cardioprotection.[20] There were 3 total cardiovascular events in this trial: 1 event (0.2%) in the rofecoxib group, 2 events (0.4%) in the nabumetone group, and no events in the placebo group.

Study 090 (N=978) was a randomized, placebo-controlled, parallelgroup, double-blind trial of the efficacy and safety of rofecoxib (12.5 mg/d) vs nabumetone (1000 mg/d) vs placebo in patients with osteoarthritis of the knee. Low-dose aspirin for cardioprotection was also allowed in this study. Study 090 reported a total of 9 serious cardiovascular events: 6 (1.5%) events in the rofecoxib group, 2 (0.5%) in the nabumetone group, and 1 (0.5%) in the placebo group.

Adverse Event Reporting System

An Adverse Event Reporting System search revealed 144 unduplicated thrombotic or embolic cases for celecoxib and 159 cases for rofecoxib.[21] Forty-two

celecoxib cases and 60 rofecoxib cases were excluded for a lack of documented event or for hemorrhagic stroke in which the prothrombin time, partial thromboplastin time, or international normalized ratio was above the normal range; also excluded were secondhand reports with no confirmed diagnosis. Ninety-nine thrombotic or embolic events were attributed to rofecoxib and 102 cases to celecoxib. Table 2 summarizes the thrombotic events reported with each agent. (Table 2: Thrombotic Adverse Events With COX-2 Inhibitors Reported in the United States has been omitted.)

Comparison With Contemporary Meta-analysis

The meta-analysis of the US Physicians' Health Study, the UK Doctors Study, the Thrombosis Prevention Trial, and the Hypertension Optimal Treatment trials included 48540 patients, of whom 25133 were treated with aspirin and 23407 were given placebo.[24] The annualized MI rate in the placebo group in this meta-analysis was 0.52%. The annualized MI rates for both the VIGOR and the CLASS trials were higher: 0.74% with rofecoxib ($P=.04$, compared with the placebo group of the meta-analysis) and 0.80% with celecoxib ($P=.02$, compared with the placebo group of the meta-analysis). (Figure 3: Comparison of MI Rates Among Subjects Receiving Placebo vs Rofecoxib or Celecoxib has been omitted.)

COMMENT

Aspirin and NSAIDs inhibit prostaglandin synthesis via a cyclooxygenase enzyme. This action is the key to both their therapeutic and toxic effects. The COX-1 isoform is constitutively expressed in most cells, which

results in the production of homeostatic prostaglandins that maintain gastrointestinal mucosal integrity and renal blood flow. The COX-1 isoform is also expressed in platelets and mediates production of thromboxane A2, a potent platelet activator and aggregator. The COX-2 isoform produces prostaglandins at inflammatory sites as well as PGI2, which is a vasodilator and inhibitor of platelet aggregation. Nonselective NSAIDs inhibit the production of both thromboxane and PGI2. Selective COX-2 inhibitors have no effect on thromboxane A2 production, but by decreasing PGI2 production may tip the natural balance between prothrombotic thromboxane A2 and antithrombotic PGI2, potentially leading to an increase in thrombotic cardiovascular events.[25, 26]

We reviewed the cardiovascular event rates in the 2 major trials with selective COX-2 inhibitors and in 2 smaller trials. The VIGOR trial demonstrated significantly increased risk of cardiovascular event rates with use of rofecoxib although the study enrolled patients who did not require aspirin for protection from ischemic events. Patients with angina, congestive heart failure, MI, coronary artery bypass graft surgery within 1 year, stroke or transient ischemic attacks within 2 years, and uncontrolled hypertension were excluded from this trial. However, these criteria can be viewed as too stringent, given data from trials that support more liberal use of aspirin for primary prevention.

The results of the VIGOR study can be explained by either a significant prothrombotic effect from rofecoxib or an antithrombotic effect from naproxen (or conceivably both). There are differential effects of NSAIDs and COX-2 inhibitors on ex vivo platelet aggregation to 1m Marachidonic acid. Naproxen has significant antiplatelet effects, with mean platelet

aggregation inhibition of 93% compared with platelet aggregation inhibition of 92% for those taking aspirin (81 mg).[22] Thus naproxen, but not ibuprofen (platelet aggregation of approximately 80%) or diclofenac (platelet aggregation of approximately 40%), resulted in a high level of platelet aggregation inhibition similar to that achieved with aspirin.[22] There is clinical evidence that flurbiprofen, 50 mg twice daily for 6 months, reduced the incidence of MI by 70% compared with placebo.[27] Indobufen, another NSAID, was as effective as aspirin in preventing saphenous vein graft occlusion after coronary artery bypass graft surgery.[28]

Because of the evidence for an antiplatelet effect of naproxen, it is difficult to assess whether the difference in cardiovascular event rates in VIGOR was due to a benefit from naproxen or to a prothrombotic effect from rofecoxib. Therefore, we examined results from a meta-analysis of 4 aspirin primary prevention trials24 to evaluate whether the cardiovascular event rates observed with rofecoxib were similar in VIGOR to a placebo-treated population with similar cardiac risk factors. While acknowledging that comparison of patient populations in 2 different trials is always problematic, the results of this meta-analysis may further demonstrate the prothrombotic potential of rofecoxib and celecoxib and suggest that increased event rates with COX-2 inhibitors are possibly due to a prothrombotic effect, not merely a failure to offer the protection of aspirinlike NSAIDs. However, it is important to point out that rheumatoid arthritis increases risk of MI, making intertrial comparisons difficult.[29]

In contrast to the VIGOR study, the CLASS study with celecoxib did not show a significant increase in

cardiovascular event rates compared with NSAIDs, possibly due to the use of lowdose aspirin in the CLASS trial or to pharmacological differences in the NSAID agents used as controls in the 2 studies. Diclofenac and ibuprofen have significantly less antiplatelet effects compared with naproxen.[22] To have a vascular protective effect, nearcomplete inhibition of thromboxane over time is needed[30] and the degree of thromboxane inhibition with diclofenac and ibuprofen may not afford cardioprotection. Furthermore, diclofenac exhibits more effect on PGI2 inhibition than does naproxen. Van Hecken et al[31] demonstrated that diclofenac causes 94% inhibition of COX-2 compared with 71% inhibition of COX-2 for naproxen. Thus, diclofenac not only has less antiplatelet effect, but may have some intrinsic prothrombotic effect among NSAIDs dueto inhibition of vasodilatory PGI2 and this may have masked the increase in event rates with celecoxib. Furthermore, the MI rate with celecoxib (0.80%) was similar to that reported with rofecoxib (0.74%) when rates were recalculated as an annualized percentage rate to enable direct comparison.

Shinmura et al[32] recently demonstrated that up-regulation of COX-2 plays an essential role in the cardioprotection afforded by the late phase of ischemic preconditioning. Administration of selective COX-2 inhibitors 24 hours after ischemic preconditioning abolished the cardioprotective effect of late ischemic preconditioning against myocardial stunning and MI.32 These data would further suggest potential deleterious cardiac effects of COX-2 inhibitors.

The availability of selective COX-2 inhibitors has raised several important clinical questions. These concern the prothrombotic potential of COX-2 inhibitors,

differences in the antithrombotic effect of various NSAIDs, the mandatory use of aspirin with selective COX-2 inhibitors, and whether simultaneous use of aspirin negates the gastrointestinal protective effect of selective COX-2 inhibitors.

Current data would suggest that use of selective COX-2 inhibitors might lead to increased cardiovascular events. Two smaller studies (Study 085 and Study 090) of rofecoxib that both allowed the use of low-dose aspirin did not demonstrate the significant increase in cardiovascular event rate noted in VIGOR. However, these studies had smaller sample sizes, used only 25% of the dose of rofecoxib used in VIGOR, and had few events for meaningful comparison. Thus the prothrombotic effect seen with rofecoxib may potentially be dose dependent. Also, the use of low-dose aspirin in these protocols may negate some of the gastrointestinal benefits of selective COX-2 inhibition. There is evidence that gastrointestinal bleeding from aspirin is not dose related.[33]

COX-2 inhibitors also have been shown to increase blood pressure,[34] and more patients in the VIGOR trial developed hypertension in the rofecoxib group compared with the naproxen group. For rofecoxib, the mean increase in systolic blood pressure in the VIGOR trial was 4.6 mm Hg and the mean increase in diastolic blood pressure was 1.7 mm Hg, compared with a 1.0-mm Hg increase in systolic blood pressure and a 0.1-mm Hg increase in diastolic blood pressure with naproxen. Changes in blood pressure in the CLASS trial were not reported. Previous work has shown that a 2-mm Hg reduction in diastolic blood pressure results in about a 40% reduction in the rate of stroke and a 25% reduction in the rate of MI.[35] The Heart Outcomes Prevention

Evaluation study demonstrated significant reduction in cardiovascular events with a 3- to 4-mm Hg reduction in blood pressure.[36] Moreover, a recent reanalysis of 20 years of blood pressure data from the Framingham Heart Study[37] suggests that the degree of benefit expected from a decrease in blood pressure may have been underestimated. Thus, the elevation in blood pressure reported with use of COX-2 inhibitors may also play an important role in adverse cardiovascular outcomes.

Based on this review, it is useful to consider nonselective and selective COX inhibitors as possessing a spectrum of biological effects, both favorable and unfavorable. At one end of the spectrum, COX-2 inhibitors show less propensity for gastrointestinal toxicity but greater prothrombotic potential. At the other end of the spectrum, aspirin and naproxen show greater potential for gastrointestinal toxicity but have a cardioprotective effect. Other agents fall along intermediate points in this spectrum. Clinicians may want to consider these patterns of risk and benefit in selecting the most appropriate agent for individual patients.

Our analysis has several significant limitations. The increase in cardiovascular events in these trials was unexpected and evaluation of these end points was not prespecified. There remains considerable uncertainty in any post hoc analysis. The patient populations in these trials were heterogeneous, and it has been established that patients with rheumatoid arthritis have a higher risk of MI.[29] This leads to difficulty in assessing risk in a more representative sampling of patients. Also, the trials we examined only addressed continuous use of COX-2 inhibitors. Currently, no data exist on cardiovascular

safety for the sporadic, intermittent use of these agents by individuals for musculoskeletal pain, which appears to be the most frequent pattern of use.

Our findings suggest a potential increase in cardiovascular event rates for the presently available COX-2 inhibitors. It is possible that concomitant use of aspirin may not fully offset the risk of selective COX-2 inhibitors. However, definitive evidence of such an adverse effect will require a prospective randomized clinical trial. On the other hand, the inflammatory component of atherosclerosis has recently been emphasized[7, 38, 39] and may be suppressible by COX-2 inhibitors. Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents. Until then, we urge caution in prescribing these agents to patients at risk for cardiovascular morbidity.

Inset from Article page 1:

Atherosclerosis is a process with inflammatory features and selective cyclooxygenase 2 (COX-2) inhibitors may potentially have antiatherogenic effects by virtue of inhibiting inflammation. However, by decreasing vasodilatory and antiaggregatory prostacyclin production, COX-2 antagonists may lead to increased prothrombotic activity. To define the cardiovascular effects of COX-2 inhibitors when used for arthritis and musculoskeletal pain in patients without coronary artery disease, we performed a MEDLINE search to identify all English-language articles on use of COX-2 inhibitors published between 1998 and February 2001. We also reviewed relevant submissions to the US

Food and Drug Administration by pharmaceutical companies.

Our search yielded 2 major randomized trials, the Vioxx Gastrointestinal Outcomes Research Study (VIGOR; 8076 patients) and the Celecoxib Longterm Arthritis Safety Study (CLASS; 8059 patients), as well as 2 smaller trials with approximately 1000 patients each. The results from VIGOR showed that the relative risk of developing a confirmed adjudicated thrombotic cardiovascular event (myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks) with rofecoxib treatment compared with naproxen was 2.38 (95% confidence interval, 1.39-4.00; $P=.002$). There was no significant difference in cardiovascular event (myocardial infarction, stroke, and death) rates between celecoxib and nonsteroidal anti-inflammatory agents in CLASS. The annualized myocardial infarction rates for COX-2 inhibitors in both VIGOR and CLASS were significantly higher than that in the placebo group of a recent meta-analysis of 23407 patients in primary prevention trials (0.52%): 0.74% with rofecoxib ($P=.04$ compared with the placebo group of the meta-analysis) and 0.80% with celecoxib ($P=.02$ compared with the placebo group of the meta-analysis).

The available data raise a cautionary flag about the risk of cardiovascular events with COX-2 inhibitors. Further prospective trial evaluation may characterize and determine the magnitude of the risk.

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Critical revision of the manuscript for important intellectual content, study supervision: Nissen, Topol. *Statistical expertise:* Mukherjee, Topol.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Raymond V. Gilmartin
President and CEO
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P.O. Box 1000, UG3BC-10
North Wales, PA 19454-1099

RE: NDA 21-042
Vioxx (rofecoxib) tablets
MACMIS ID # 9456

WARNING LETTER

Dear Mr. Gilmartin:

This Warning Letter concerns Merck & Co. Inc.'s (Merck) promotional activities and materials for the marketing of Vioxx (rofecoxib) tablets. Specifically, we refer to promotional audio conferences given on behalf of Merck by Peter Holt, MD, a press release, and oral representations made by Merck sales representatives to promote Vioxx. As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed your promotional activities and materials and has concluded that they are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f), and (n), and 355 (a).

You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).

Although the exact reason for the increased rate of MIs observed in the Vioxx treatment group is unknown, your promotional campaign selectively presents the following hypothetical explanation for the observed increase in MIs. You assert that Vioxx does not increase the risk of MIs and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. That is a possible explanation, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties.

You have also engaged in promotional activities that minimize the Vioxx / Coumadin (warfarin) drug interaction, omit important risk information, make unsubstantiated superiority claims against other NSAIDs, and promote Vioxx for unapproved uses and an unapproved dosing regimen. In addition, in misrepresenting the Vioxx / warfarin drug interaction you also misrepresent Vioxx's safety profile by minimizing the potentially serious risk of significant bleeding that can result from using Vioxx and warfarin concomitantly.

Your minimizing these potential risks and misrepresenting the safety profile for Vioxx raise significant public health and safety concerns. Your misrepresentation of the safety profile for Vioxx is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for Vioxx that also misrepresented Vioxx's safety profile.

Background

Vioxx is a NSAID with selective cyclooxygenase 2 (COX-2) inhibitory properties. It was approved on May 20, 1999, for the treatment of primary dysmenorrhea, for the management of acute pain in adults, and for relief of the signs and symptoms of osteoarthritis.

Prior to approval, endoscopy studies were submitted to the original NDA database demonstrating that treatment with Vioxx 25 mg or 50 mg daily was associated with a significantly lower percentage of endoscopically apparent gastroduodenal ulcers than treatment with ibuprofen 2400 mg daily. Because the correlation between findings of endoscopic studies and the relative incidence of clinically serious upper gastrointestinal (GI) events was unknown, after approval, Merck sponsored the VIGOR study to obtain information regarding clinically meaningful upper GI events and to develop a large controlled database for overall safety assessment.

The VIGOR study included approximately 4000 patients per treatment arm (Vioxx 50 mg a day or naproxen 1000 mg a day) treated for a median time of 9 months. The primary endpoint of the study was the relative risk of confirmed PUBs (perforations, symptomatic ulcers, and GI bleeds) in patients with rheumatoid arthritis taking

Vioxx 50 mg daily (two to four times the approved dosing regimen for Vioxx in osteoarthritis), compared to patients taking naproxen, 1000 mg daily. The study also compared the safety and tolerability of the two treatments in patients with rheumatoid arthritis. The results of the study demonstrated that patients on Vioxx had a significantly lower cumulative incidence of PUB's compared to patients on naproxen (2.08% and 4.49% for Vioxx and naproxen, respectively).

Other important results from the VIGOR study included the unexpected findings that investigator reported serious cardiovascular events occurred in 101 patients (2.5%) in the Vioxx treatment group compared to 46 patients (1.1%) in the naproxen treatment group, and MIs occurred in 20 patients among 4047 in the Vioxx treatment group (0.5%), compared to four patients among 4029 in the naproxen treatment group (0.1%). These unexpected findings were extensively discussed at the FDA Arthritis Advisory Committee Meeting on February 8, 2001. Although, the reason for these differences is not clear, possible explanations include both an ability of naproxen to function as a cardioprotective agent and a pro-thrombotic property of Vioxx.

Promotional Audio Conferences

We are aware of six promotional audio conferences, presented on behalf of Merck by Peter Holt, MD that are in violation of the Act and its implementing regulations. These audio conferences were held on June 8, 2000, June 13, 2000, June 16, 2000, and three on June 21, 2000, and were moderated by Merck employees.

On December 12, 2000, we sent you a written inquiry about your involvement with and influence on the initiation, preparation, development, and publication of audio conferences given by Dr. Holt. We also asked you to describe the nature of the relationship between you and Dr. Holt. In your response dated January 5, 2001, you stated that, "Dr. Holt entered into a speaker contract with Merck on June 22, 1999." You also stated that, "Merck has determined that we arranged for Dr. Holt to speak at ten audio conferences in 2000. Merck Business Managers provided him with the topic for the audio conferences and, for two of the audio conferences, asked him to address the safety profiles of Vioxx and other NSAIDs."

The promotional audio conferences identified above, arranged by, and presented on behalf of, Merck were false or misleading in that they minimized the MI results of the VIGOR study, minimized the Vioxx / Coumadin drug interaction, omitted important risk information, made unsubstantiated superiority claims, and promoted Vioxx for unapproved uses and an unapproved dosing regimen. Our specific objections follow.

Minimization of MI Results

Statements made during the promotional audio conferences identified above minimize the potentially serious MI risk that may be associated with Vioxx therapy. For example, in your June 21, 2000 audio conference you begin your discussion of the MI rates observed in the VIGOR study by stating, "When you looked at the MI rate the rate was different for the two groups. The MI rate for Vioxx was 0.4 percent and if you looked at the Naprosyn arm it was 0.1 percent, so there was a reduction in MIs in the Naprosyn group." You

then present your explanation as to why the Vioxx treatment arm had an increased rate of MIs compared to the naproxen treatment arm. Specifically, you state that,

> Vioxx is a wonderful, effective, selective COX-2 inhibitor that inhibits COX-2 but at the doses used does not inhibit COX-1. So therefore without the COX-1 inhibition you don't inhibit platelets, you don't prolong bleeding time and therefore it cannot be used as a cardiovascular protective drug. Naprosyn on the other hand is a wonderful platelet inhibitor, prolongs bleeding time and inhibits platelets identically to aspirin. Obviously the binding with Naprosyn is reversible and with aspirin is irreversible, but the effect on platelets and bleeding time is identical in terms of its effect and therefore functions as a wonderful drug for cardiovascular prophylaxis. So basically the MI rates are in sync with what we know about Vioxx and what we know about Naprosyn.

In fact, the situation is not at all clear. There are no adequate and well-controlled studies of naproxen that support your assertion that naproxen's transient inhibition of platelet aggregation is pharmacodynamically comparable to aspirin or clinically effective in decreasing the risk of MIs. Therefore, your representation that naproxen prolongs bleeding time and inhibits platelets identically to aspirin is misleading, and minimizes the potential seriousness of this finding. As you know, the reason for the difference between Vioxx and naproxen has not been determined; it is also possible that Vioxx has pro-thrombotic properties. Also, the MI

rate that you report for Vioxx is inaccurate; the MI rate for Vioxx in the VIGOR study was 20 MIs among 4047 patients (0.5%), not 0.4%, as you stated.

Your minimization of the seriousness of the MI rates observed in the Vioxx treatment arm of the VIGOR trial is further reinforced in your audio conferences by your discussion of a retrospective analysis of this trial. For example, in your June 21, 2000, audio conference, you state that,

> ... Merck went and pulled out those patients that again were enrolled in VIGOR and asked the question, who were those patients that really needed secondary cardiovascular prophylaxis from the get go, and that ended up being four percent of the study group in VIGOR based on whether there was a prior MI, stroke, TIA, angina, CABG or PTCA....Now if you look at the remaining part of VIGOR, which is 96 percent of the VIGOR population, and once again looked for the MI rate between Naprosyn and Vioxx, there's no statistically significant difference in the MI rate between Naprosyn and Vioxx. In fact, Naprosyn is 0.2 percent and Vioxx is 0.1 percent.

Your claim that the MI rate for naproxen was 0.2 percent and for Vioxx was 0.1 percent is again inaccurate. Contrary to your claim that there was a higher rate of MIs in the naproxen group compared to the Vioxx group, the MI rate for Vioxx in this subpopulation was 12 MIs among 3877 patients (0.3%) as

compared to 4 MIs among 3878 patients (0.1%) for naproxen.

Moreover, you again minimize the Vioxx MI rate observed in the VIGOR study by your comparison of this rate to the rate of MIs observed for Celebrex (celecoxib) in the Celebrex Long-Term Arthritis Safety Study (CLASS). For example, in your June 21, 2000, audio conference you state, "Now if you remember the crude MI rate of Vioxx in VIGOR that number was 0.4 percent which is basically the same or in fact a little bit less then the crude MI rate of Celebrex in CLASS which is 0.5 percent." Your claim that the MI rates of Vioxx compared to Celebrex were basically the same, "or in fact a little bit less" is misleading. You are comparing MI rates from two different trials with different patient populations. For example, patients who had angina or congestive heart failure with symptoms that occurred at rest or minimal activity and patients taking aspirin, including low-dose (325 mg or less, daily or every other day) or other antiplatelet agents (e.g., ticlopidine) were excluded from the VIGOR trial. The CLASS trial in contrast, did not exclude patients of this type. The CLASS trial thus may have included patients at a higher risk for MIs.

Minimization of Vioxx / Coumadin Interaction

Statements made during your promotional audio conferences also minimize the risk of Viaxx therapy in patients who are taking warfarin. For example, in your June 16, 2000, audio conference you stated that, " . . . if you look at the thromboembolic events it's very clear that these selective COX-2 inhibitors have the benefit of not having platelet aggregation and bleeding time, and therefore, can be used safely in terms of post-op and

with Coumadin." Your statement that Vioxx can be used safely with warfarin minimizes the precaution in the PI that states that "...in post-marketing experience, bleeding events have been reported, predominately in the elderly, in association with increases in prothrombin time in patients receiving Vioxx concurrently with warfarin." Your promotion minimizing the risk of using Vioxx and warfarin concurrently is particularly troublesome because Merck was aware of this potentially dangerous drug interaction in 1999, well before these audio conferences occurred. In fact, Merck began disseminating a revised PI in October 1999, which included new information about this risk.

The seriousness of this interaction is further minimized by your suggestion that COX-2 inhibitors, including Vioxx, can be used safely with warfarin because it "has the benefit of not having platelet aggregation and bleeding time." This claim implies that Vioxx is safer than other NSAIDS used in combination with warfarin. However, Vioxx has not been studied in head-to-head trials prospectively designed to assess this specific endpoint. Your superiority claim is therefore misleading.

We note that earlier in your June 16, 2000, promotional audio conference you state, "It can be used in people with Coumadin, although with Coumadin you've got to check their INR three and four days after you add the Cox inhibitor to the Coumadin because there may be a bump in the INR." This disclosure does not correct the overall misleading message, however, nor does it correct your suggestion that Vioxx is safer than other NSAIDs in patients taking warfarin.

Omission of Important Risk Information

Your promotional audio conferences fail to present serious and significant risks associated with Vioxx therapy. For example, your promotional audio conferences fail to state that Vioxx is contraindicated in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. You also fail to present the gastrointestinal (GI) warning about the possibility of serious GI toxicity such as bleeding, ulceration, or perforation in patients taking Vioxx. Moreover, you fail to present Vioxx's precautions for use in patients who have liver and kidney disease, information about patient populations in which Vioxx's use is not recommended, such as women in late pregnancy, and information about Vioxx's most common adverse events.

Unsubstantiated Superiority Claims

You make several unsubstantiated superiority claims for Vioxx throughout your promotional audio conferences. For example, in your June 16, 2000, audio conference, you claim that, "The importance of [VIGOR and CLASS] is that the data is going to really help change I believe the package inserts for [Vioxx and Celebrex] down the road because it really shows once again that they are safer than nonsteroidals." Your suggestion that COX-2 inhibitors, including Vioxx, have an overall safety profile that is superior to other NSAIDs is misleading because such an advantage has not been demonstrated. In fact, in the VIGOR study the incidence of serious adverse events was higher in the Vioxx treatment group than in the naproxen treatment group (9.3% and 7.8% for Vioxx and naproxen, respectively). The results of safety analyses that were pre-specified in the protocol for the VIGOR

trial, such as CHF-related adverse events and discontinuations due to edema-related adverse events, hepatic-related adverse events, hypertension-related adverse events, and renal-related adverse events were all numerically higher (in some cases statistically significantly higher) in the Vioxx treatment group than in the naproxen treatment group. Furthermore, your claim that the VIGOR and CLASS trials "show once again that they are safer than non-steroidals" is also misleading because it implies that the results of the VIGOR trial (i.e., patients on Vioxx had a significantly lower cumulative incidence of PUBs than patients on naproxen) can be applied to the entire class of NSAIDs.

In your June 16, 2000, audio conference you state, " . . . if you look at the thromboembolic events it's very clear that these selective COX-2 inhibitors have the benefit of not having platelet aggregation and bleeding time, and therefore, can be used safely in terms of post-op and with Coumadin." This claim suggests that Vioxx is safer, or has fewer side effects, than other NSAIDs used in the post-operative setting because COX-2 inhibitors do not affect platelet aggregation and bleeding time. Vioxx has not been studied, however, in head-to-head trials prospectively designed to assess its safety compared to other NSAIDS in the post-operative setting. Your superiority claim is therefore misleading.

Further examples of your unsubstantiated superiority claims include your claim that, "In terms of half life Vioxx has a half life of 17 hours and is truly a once a day drug, whereas Celebrex has a half life of 11 hours and is a BID (twice a day) drug," stated in your June 16, 2000, audio conference. This claim is misleading because it suggests that Celebrex must be dosed twice a day for all of its approved indications. In fact, Celebrex is approved

for use either twice a day, or once a day, for the treatment of osteoarthritis. Therefore, your claim that Celebrex is a "BID drug" is misleading.

Promotion of Unapproved Uses

Your audio conferences are misleading because they promote Vioxx for unapproved uses. For example, in your June 21, 2000, conference, you claim that in the VIGOR study, ". . . the Vioxx 50 milligrams a day and the Naprosyn, a gram a day, were absolutely equally effective in terms of treating the patients with rheumatoid arthritis." Your claim is misleading because it suggests that Vioxx is effective for the treatment of rheumatoid arthritis when this has not been demonstrated. The VIGOR study was not designed to assess the efficacy of Vioxx for the treatment of rheumatoid arthritis. Your claim that Vioxx is "absolutely equally effective" to naproxen in treating patients with rheumatoid arthritis is also misleading because this has not been demonstrated by adequate and well-controlled clinical studies, and because the VIGOR study was not capable of assessing their comparative effectiveness.

Your promotional audio conferences are also misleading because they suggest that Vioxx is safe and effective for other unapproved uses such as the prevention of cancer and invasive cancer, and for the treatment of Alzheimer's disease and gout. Examples of claims that promote Vioxx for unapproved uses, include, but are not limited to, your claims in your June 16, 2000 audio conference that, " . . . COX-2 seems to be able to interfere with . . . programmed cell death. Therefore, you get this increased cell growth which allows polps [*sic*] to form, cancer and then invasive cancer. And by blocking COX-2

you can actually prevent the development of colon polyps, cancer and invasive cancer." Additional examples include your claims that "So we tried it [Vioxx] after Vioxx was released and really within one or two pills acute attacks of gout were being shut down," and "Specifically, if you looked at potential uses of these drugs, the most exciting right now I guess in two areas, one is Alzheimer's disease . . .."

Press Release

We have identified a Merck press release entitled, "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx," dated May 22, 2001, that is also false or misleading for similar reasons stated above. Additionally, your claim in the press release that Vioxx has a "favorable cardiovascular safety profile," is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDs is misleading; in fact, serious cardiovascular events were twice as frequent in the VIOXX treatment group (101 events, 2.5%) as in the naproxen treatment group (46 events, 1.1%) in the VIGOR study.

Oral Representations

Merck sales representatives have engaged in false or misleading promotional activities that also minimize the potentially serious MI results observed in the VIGOR trial. Specifically, Merck sales representatives made false or misleading statements to DDMAC reviewers at two different professional meetings. At your exhibit booth during the 119th Annual Meeting of the Maryland Pharmacists Association (MPhA), in Ocean City,

Maryland, June 9 - June 12, 2001, your representative stated that the increased MI rate seen in patients on Vioxx in the VIGOR study is due to the fact that naproxen works just like aspirin (i.e., inhibits clotting and platelet aggregation). In addition, during the Annual Meeting of the American Society of Health-Systems Pharmacists (ASHP), in Los Angeles, California, June 3 - June 6, 2001, your representative stated that Vioxx had a greater MI rate in the VIGOR trial because naproxen is cardioprotective, having platelet effects similar to aspirin. These statements made by your sales representatives are misleading for the reasons stated above.

Conclusions and Requested Actions

The promotional activities and materials described above minimize the potentially serious cardiovascular findings that were observed in the VIGOR study, minimize the Vioxx / Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for Vioxx that misrepresented Vioxx's safety profile, contained unsubstantiated comparative claims, and lacked fair balance.

Due to the seriousness of these violations, and the fact that your violative promotion of Vioxx has continued despite our prior written notification regarding similar violations, we request that you provide a detailed response to the issues raised in this Warning Letter on or before October 1, 2001. This response should contain an action plan that includes a comprehensive plan to disseminate corrective messages about the issues

discussed in this letter to the audiences that received these misleading messages. This corrective action plan should also include:

Immediately ceasing all violative promotional activities, and the dissemination of violative promotional materials for Vioxx.

Issuing a "Dear Healthcare provider" letter to correct false or misleading impressions and information. This proposed letter should be submitted to us for review prior to its release. After agreement is reached on the content and audience, the letter should be disseminated by direct mail to all healthcare providers who were, or may have been exposed to the violative promotion.

A written statement of your intent to comply with "1" and "2" above.

Your written response should be received no later than October 1, 2001. If you have any questions or comments, please contact Lesley Frank, Ph.D., JD, by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. We remind you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #9456 in addition to the NDA number.

The violations discussed in this letter do not necessarily constitute an exhaustive list. We are continuing to evaluate other aspects of your promotional campaign for Vioxx, and may determine that additional remedial messages will be necessary to fully correct the false or misleading messages resulting from your violative conduct.

Failure to respond to this letter may result in regulatory action, including seizure or injunction, without further notice.

Sincerely,
{*See appended electronic signature page*}
Thomas W. Abrams, R.Ph., MBA
Director
Division of Drug Marketing,
Advertising, and Communications

Biotech Week
April 12, 2000

RHEUMATOID ARTHRITIS: PRELIMINARY RESULTS OF GASTROINTESTINAL OUTCOMES STUDY PRESENTED

2000 APR 12 — (NewsRx.com & NewsRx.net) Merck & Co., Inc. (MRK), West Point, Pennsylvania, informed its investigators of a preliminary analysis from a large gastrointestinal (GI) outcomes study that compared Vioxx (rofecoxib) with naproxen in patients with rheumatoid arthritis.

Among patients treated with Vioxx, there was a significantly reduced incidence of serious gastrointestinal events compared to patients treated with naproxen. Merck plans to submit the information to the U.S. Food and Drug Administration (FDA) and other regulatory agencies worldwide in the next few months.

In addition, significantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation. This effect on these events had not been observed previously in any clinical studies for naproxen.

Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects. As a result, Merck is notifying investigators, who are conducting other Merck studies with Vioxx or another investigational medicine in the same class, of protocol amendments to allow the addition of low-dose aspirin where appropriate. Patients using low-dose aspirin, which also blocks platelet

aggregation, were excluded from the GI outcomes study. Vioxx does not interfere with the ability of low-dose aspirin to block platelet aggregation.

The completed study, called VIGOR (Vioxx Gastrointestinal Outcomes Research), compared the GI safety of Vioxx (50 mg once daily) to prescription-strength naproxen (500 mg twice a day) in approximately 8,000 patients with rheumatoid arthritis. The study specifically assessed the incidence of certain types of clinically significant upper GI events, including perforations, ulcers, obstructions, and bleeds.

Naproxen is a commonly used non-steroidal anti-inflammatory drug (NSAID) indicated for the treatment of a number of arthritic diseases, including rheumatoid arthritis. Vioxx is not approved for the treatment of rheumatoid arthritis, nor is an application for this use under review. Vioxx is approved in the U.S. for the relief of the signs and symptoms of osteoarthritis, management of acute pain in adults, and treatment of menstrual pain.

Researchers believe that NSAIDs work by inhibiting two related enzymes: COX-1, the enzyme that helps maintain the stomach lining and promotes platelet aggregation, and COX-2, the enzyme that triggers pain and inflammation. At therapeutic doses, Vioxx works by selectively inhibiting COX-2 without inhibiting COX-1; non-selective NSAIDs like naproxen inhibit both COX-1 and COX-2. Medicines like aspirin and naproxen that significantly inhibit COX-1 block platelet aggregation and therefore have the potential to provide cardioprotection.

An extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-

marketing experience with Vioxx, showed no indication of a difference in the incidence of thromboembolic events between Vioxx, placebo, and comparator NSAIDs.

Further analyses are ongoing, and final results of the GI outcomes study with Vioxx have been scheduled for presentation at peer-reviewed medical meetings in 2000.

This article was prepared by Biotech Week editors from staff and other reports.

Reuters
April 27, 2000

MERCK'S VIOXX SEEN FACING FDA SCRUTINY ON HEART ATTACKS

BY RANSDELL PIERSON

NEW YORK, April 27 (Reuters) - Merck & Co.'s arthritis drug Vioxx, taken by more than six million Americans since its 1999 debut, is likely to face stepped-up scrutiny from U.S. regulators because of the number of patients who suffered strokes and heart attacks after taking the medicine in new clinical trials, analysts said.

"The heart attacks and strokes could be a serious concern for the Food and Drug Administration, and could delay or derail Merck's plans to market Vioxx for rheumatoid arthritis," said David Saks, manager of Gruntal & Co's Medical Sciences Fund.

The FDA in recent months has shown far more concern over safety of drugs already on the market and those awaiting approval, following the recall of several medicines linked to deaths and serious side effects.

Vioxx is one of the fastest-selling new drugs in the world. It was approved last May by the FDA for the treatment of acute pain and osteoarthritis - the most common form of arthritis, caused by normal wear and tear of joints and afflicting 21 million Americans. Some analysts expect sales of Vioxx, which were worth $472 million last year, to swell to $2 billion or more by 2002.

MERCK SEEKS WIDER MARKET

The No. 1 U.S. drugmaker has said it plans to soon ask the FDA to widen the approved use of Vioxx to rheumatoid arthritis, the crippling hereditary form of arthritis afflicting 2.1 million Americans, in which the body's own immune system attacks joints.

In late March, Merck said in a statement that preliminary data from a study of 8,000 rheumatoid arthritis patients showed those taking Vioxx suffered far fewer ulcers and other gastrointestinal side effects than those who took a popular older arthritis drug called naproxen.

But Merck said patients using naproxen - a generic painkiller made by many companies which is in the same family as aspirin - had significantly fewer heart attacks and strokes than the Vioxx group. Merck has attributed that negative finding for Vioxx to naproxen's ability to prevent platelets from sticking together. Such platelet clumping can cause blood clots. That study did not include a placebo comparison.

NEW RISK ELEMENT

Some analysts, though, are less than convinced by Merck's explanation.

"This whole situation about heart attacks and strokes adds an element of risk to Vioxx that most people are not looking at. It's not on most people's radar screens, but it should be," said Mario Corso, a Boston-based drug analyst for Dutch bank ABN-Amro.

Gruntal's Saks - who had previously forecast Vioxx could achieve annual sales of $2 billion by 2002, including

between $200 million and $300 million for rheumatoid arthritis if it wins that approval - says FDA scrutiny could threaten those sales prospects.

"The rheumatoid arthritis indication would be icing on the cake. The larger question is how this issue (of heart attacks and strokes) might affect the whole cake," he said, referring to the drug's total sales.

FDA spokesperson Susan Cruzan told Reuters she could not comment on how closely her agency might scrutinise Merck's rheumatoid arthritis marketing application and the related heart attack and stroke data.

"It's too early to comment about that. We will review the study and the results for both drugs," Cruzan said, referring to comparisons between Vioxx and naproxen.

Meanwhile, Cruzan said the FDA continues to believe that Vioxx is "effective and adequately safe" for its labeled uses.

The FDA has overseen a spate of drug recalls in the past three years, nudging companies to voluntarily withdraw their medicines after side effects rarely seen in clinical trials became apparent once the drugs hit the market and were taken by millions of people.

On March 23, Johnson & Johnson said it would severely limit sales of its blockbuster heartburn medicine Propulsid following reports of heart rhythm abnormalities and 80 deaths among users. Only days earlier, Warner-Lambert Co. withdrew its Rezulin diabetes drug, which the FDA said had been linked to 63 deaths from liver failure.

The FDA drew criticism from many quarters, including the CBS television programme "60 Minutes," for allowing Rezulin to remain on the market despite

mounting liver abnormalities and deaths among users. The agency has also been accused of ignoring serious side effects linked to two American Home Products Corp. diet drugs used in the once-popular "fen-phen" slimming cocktail.

AHP's drugs - Pondimin (fenfluramine) and Redux (dexfenfluramine) - were recalled in 1997 after being linked to heart valve problems in some of the six million Americans who had taken the diet suppressants.

CLEAR TREND

On Wednesday, Merck spokeswomen Jan Weiner told Reuters the fewer heart attacks and strokes in the naproxen group, compared to Vioxx, was a "statistically significant" finding - a scientific term meaning it was a clear trend.

But Weiner said there was no evidence Vioxx had actually put patients at higher risk of such adverse events. Instead, she said it was likely that naproxen had conferred protection to patients taking that drug.

"Naproxen blocks platelet aggregation, it keeps them from clumping together. That's in the literature," Weiner said, referring to previous medical studies.

As a testament to Vioxx, Weiner said the drug did not show any such higher incidence of heart attacks and stroke in separate studies of osteoarthritis patients and acute pain studies that pitted it against other popular painkillers such as ibuprofen and diclofenac.

Swiss drugmaker Roche Holding Ltd is among the largest sellers of naproxen. Its product is sold under the brand name Naprosyn.

"To our knowledge, naproxen does not prevent heart attack or stroke," Shelley Rosenstock, a U.S. spokesperson for Roche told Reuters.

ABN Amro's Corso said he was not reassured by Merck's suggestion that naproxen conferred protection against heart attacks and strokes.

"Medical authorities I've spoken to don't see any special reduction of such cardiovascular events in people taking naproxen," Corso said.

"This could conceivably delay approval of Vioxx for rhematoid arthritis. The FDA could ask for another trial to see if the results were a fluke or to add more validity to the findings," he said.

Vioxx is a member of a new family of drugs that selectively block the so-called Cox-2 enzyme linked to pain and inflammation. Its 1999 global sales of $472 million, included U.S. revenues of $420 million. Wall Street expects worldwide annual sales of $2 billion by 2002.

Vioxx is locked in a fierce battle with Celebrex, a Cox-2 inhibitor sold by New Jersey drugmaker Pharmacia Corp. that had 1999 sales of $1.5 billion. Both Cox-2 drugs are rapidly stealing market share from naproxen, aspirin and other painkillers called nonsteroidal anti-inflammatory drugs (NSAIDs).

The NSAIDs inhibit Cox-2, but also block the Cox-1 enzyme which protects the stomach lining - and thus cause over 16,000 deaths in the United States from ulcers and related problems each year. Vioxx and Celebrex, because they ignore Cox-1, are considered much milder on the stomach.

Dr. Steven Geis, a senior researcher for Pharmacia's G.D. Searle pharmaceuticals unit, said Celebrex showed no such higher incidence of heart attacks and strokes when it was also tested against naproxen.

Geis said about 8,000 patients who had osteoarthritis and rheumatoid arthritis participated in the Searle trials, with half taking Celebrex and half taking naproxen.

"We found no differences in the incidence of heart attacks and strokes in patients taking Celebrex and naproxen," Geis said. Moreover, Geis said there was no evidence that any NSAID, with the exception of aspirin, prevents heart attacks or stroke.

Bloomberg News
April 28, 2000

MERCK'S VIOXX PAINKILLER MAY FACE SCRUTINY FROM FDA, CNBC SAYS

Merck & Co., the world's biggest drugmaker, may face safety questions from the U.S. Food and Drug Administration about one of its most important medicines, the painkiller Vioxx, CNBC reported.

The U.S. regulators may be concerned about the number of patients who took the drug during clinical studies and have suffered strokes or heart attacks, CNBC said, citing analysts. Merck officials couldn't immediately be reached for comment.

Vioxx is one of the new medicines Merck is counting on to help it overcome generic competition for top-selling drugs. Four products with 1999 U.S. sales of $3 billion will lose patent protection by mid-2002.

Merck introduced Vioxx in 1999, about six months after a rival drug, Celebrex, now owned by Pharmacia Corp. In the first quarter, Celebrex sales rose about 6.8 percent to $534 million from about $500 million in the fourth quarter, while Vioxx sales climbed 40 percent to $370 million.

Bloomberg News
April 28, 2000

MERCK FALLS ON VIOXX CONCERNS; COMPANY DENIES RISK

Merck & Co. shares fell 2.8 percent after reports cited analyst concerns that the U.S. Food and Drug Administration might toughen its stance toward the painkiller Vioxx.

Merck shares fell 2 to close at 69 1/2 on the New York Stock Exchange. Investor worries stemmed from a study, first reported March 27, that found patients taking Vioxx had a higher incidence of stroke or heart attack than patients on a generic painkiller, naproxen. CNBC and Reuters said analysts thought the study could trigger regulatory scrutiny of Vioxx.

Merck, the world's No. 1 drugmaker, said a review of all of its Vioxx studies didn't indicate patients taking the drug were at any higher risk of heart problems than those of similar medicines or a placebo. Still, investors are alert to any suggestion of trouble for drugmakers, because FDA safety concerns have led to setbacks for three drugs since March.

"People are beginning to wonder if the FDA isn't getting a little tougher," said Jack Lafferty, an analyst with U.S. Trust, which holds about 13 million Merck shares, according to regulatory filings.

The FDA considers Vioxx to be safe and plans to review data from the March 27 study, said spokeswoman Susan Cruzan. The FDA considers Vioxx and naproxen "to be effective and adequately safe for their labeled uses and will examine the findings of the new study to evaluate possible changes in prescribing information,"

Cruzan said The March 27 study, called the Vigor study, didn't suggest Vioxx caused heart attack or stroke. Patients on Vioxx may have experienced more heart problems because other patients in the study were getting some heart benefit from naproxen, which has blood-thinning effects similar to those of aspirin, Merck said.

Of about 4,000 patients given naproxen, 0.1 percent had heart attacks compared to 0.5 percent of about 4,000 patients on Vioxx, Merck said. In a separate study of Pharmacia Corp.'s Celebrex, a painkiller in the same class as Vioxx, 0.5 percent of patients on Celebrex and ibuprofen had heart attacks, compaed with 0.3 percent for those on another painkiller, diclofenac, Merck said.

Vioxx is crucial to Merck's earnings growth as it faces the loss of patent protection by mid 2002 on drugs with about $3 billion in 1999 U.S. sales.

Other Drug Setbacks

Investor worries about Vioxx come a week after Bristol-Myers Squibb Co. delayed for at least a year its introduction of a potential blockbuster heart pill Vanlev because of FDA concerns about side effects. The news sent Bristol-Myers shares plunging 22 percent

In March, Warner-Lambert Co. took its diabetes pill Rezulin off the market under FDA pressure after the drug was linked to liver damage and more than 60 deaths. That month, Johnson & Johnson agreed to limit U.S. marketing of its Propulsid ulcer drug because of FDA concerns about its link to heart problems.

Investors and analysts have said they will be paying close attention as Merck presents the results of the Vigor study at a medical meeting in San Diego May 21-

24. Merck is using this study as part of its effort to win approval to market Vioxx for expanded use in rheumatoid arthritis patients.

Further review of findings from all Merck's Vioxx studies found no difference in heart problems between patients who took Vioxx, and those on other painkillers including naproxen, or on a placebo, Merck said. The company also said it has seen no sign of ties to cardiac problems in the more than 6 million patients who have so far taken the drug.

No Difference

"In one particular study, the Vigor study, there was a difference in favor of naproxen, but looking at the database overall, there was no difference," said Jan Weiner, a Merck spokeswoman.

Reuters yesterday reported analyst concerns stemming from the study results. In reporting that study, Merck said that it was advising investigators in other studies of the drug to allow patients taking Vioxx to also take a low dose of aspirin, which is known to protect the heart. Patients in that study weren't originally allowed to use aspirin.

Naproxen doesn't have documented protective effects on the heart, however, it does block the clumping of blood cells known as platelets, which in other drugs such as aspirin has shown benefits to the heart. That may be the reason patients on naproxen had fewer heart problems in the Vigor study, one of the largest and longest to use naproxen, Merck said.

Lehman Brothers analyst Tony Butler, who pointed the different rate of cardiac problems in a note to investors when the Merck study was released in March,

said that any conclusions about a cardiac effect of Vioxx based on that data would be very premature. Butler called the data "positive."

"To conclude that Vioxx increases cardiac risk based on Merck's comments about aspirin and on a comparison across trials is an extremely aggressive conclusion. And it may be true, but it is far too soon to make that kind of judgment." Butler said. "I have a hard time making those assumptions based on the data that we have." Merck introduced Vioxx in 1999, about six months after Celebrex. In the first quarter, Celebrex sales rose about 6.8 percent to $534 million from about $500 million in the fourth quarter, while Vioxx sales climbed 40 percent to $370 million.

Pharmacia issued a release this afternoon saying that its own recent study of Celebrex failed to turn up any higher rate of cardiac trouble among patients who took the drug, compared to patients taking other agents. That study also failed to find Celebrex was safer on the stomach than other painkillers.

Pharmacia shares fell 2 15/16, or 5.6 percent, to close at 49 15/16 on the New York Stock Exchange.

Neither Celebrex nor Vioxx is considered to be "cardioprotective," and the drugs carry identical labeling advising doctors not to substitute either medicine for aspirin for use as cardiovascular protection.

Dow Jones & Reuters
April 28, 2000

MERCK FALLS ON SAFETY CONCERNS FROM VIOXX ARTHRITIS TRIAL

BY RANSDELL PIERSON

NEW YORK, April 28 (Reuters) - Shares of Merck & Co fell Friday amid Wall Street concerns about a study that cast some doubt about the safety of the company's blockbuster arthritis drug Vioxx compared with an older commonly used treatment for the disease.

The shares lost 3-1/2 to 68, or about 5 percent, in heavy afternoon trading on the New York Stock Exchange.

Analysts on Thursday told Reuters they were concerned about a Merck study of 8,000 rheumatoid arthritis patients in which patients taking Vioxx had more heart attacks than those taking a generic arthritis drug called naproxen.

Merck released preliminary data late last month on the rheumatoid arthritis study, attributing the negative finding for Vioxx to naproxen's ability to prevent platelets from sticking together. Such platelet clumping can lead to blood clots.

On Friday, Merck officials said they further reviewed the preliminary data late Thursday and determined that Vioxx patients did not in fact have a meaningfully higher incidence of stroke. But the company reaffirmed that Vioxx users in the trial indeed had a "statistically significant" higher number of heart attacks than the naproxen group.

The head-to-head study of the two drugs cast much positive light on Vioxx, however, showing the Vioxx group suffered far fewer ulcers and gastrointestinal problems than the group taking naproxen, which is sold by Swiss drugmaker Roche Holding Ltd and other companies.

"At this point, it is not crystal clear that Vioxx is the perfectly pure drug everyone had thought it to be. At first blush, the (Vioxx vs. naproxen) trial would definitely raise an eyebrow" about its safety relative to naproxen, said Chase Hambrecht & Quist analyst Corey Davis.

"But it's way too soon to say there's any negative aspect to Vioxx," Davis said, adding that a clearer picture will emerge next month when Merck releases full data on the large rheumatoid arthritis trial.

Davis said he remained quite confident about Vioxx' overall safety, however, because previous studies comparing it with other popular arthritis drugs, as well as with placebos, showed no difference in the incidence of heart attacks and other thromboembolic events - instances in which blood vessels are blocked by clots. Those studies involved patients with osteoarthritis and acute pain.

Vioxx and a rival drug sold by Pharmacia Corp., Celebrex, are members of a new family of arthritis drugs that work by selectively inhibiting the so-called Cox-2 enzyme, which has been linked to inflammation and pain.

Naproxen, aspirin, ibuprofen and other nonsteroidal anti-inflammatory drugs (NSAIDs) also block Cox-2, but are believed to cause a much higher number of ulcers and gastrointestinal problems because they also block the related Cox-1 enzyme, which protects the stomach lining.

Mary Elizabeth Basaman, a Merck spokeswoman, said on Friday a difference in such thromboembolic events had only been seen in the rheumatoid arthritis study that compared Vioxx with naproxen - but not in trials of thousands of patients that compared Vioxx with other NSAIDs and placebos.

Hemant Shah, an independent New Jersey analyst, said he shared Merck's belief that Vioxx itself probably does not increase heart attacks and other cardiovascular problems, but that naproxen patients probably had fewer attacks because the older drug likely has "cardio-protective" traits.

Nevertheless, Shah said, the trial results were significant. He said they indicate that patients now switching from aspirin, naproxen and other NSAIDs to Vioxx and Celebrex in order to minimise their ulcer risk, might in the process be losing some cardio-protective benefits of the older NSAIDs.

"It's an interesting dilemma. There's no question Vioxx has lower gastrointestinal side effects than NSAIDs, but there's also no question that NSAIDs offer cardio-protective benefits that patients aren't getting from Vioxx," Shah added.

Vioxx is now approved for acute pain and osteoarthritis, the more common form of arthritis that is caused by wear and tear of joints. Merck has said it plans soon to seek U.S. marketing approval of the drug for rheumatoid arthritis, the less common, crippling form of arthritis in which the body's immune system attacks joints.

In view of the Vioxx-vs.-naproxen study, Shah and other analysts have said they expect the U.S. Food and Drug Administration to give especially careful scrutiny

to Merck's application to expand use of Vioxx to rhematoid arthritis, which affects an estimated 2.1 million Americans.

He speculated the FDA might require that patients taking Vioxx also take low doses of aspirin, which Shah said has demonstrated clear ability to prevent heart attacks and other cardiovascular problems.

"Ironically, patients would be taking a Cox-2 inhibitor (Vioxx) to escape gastrointestinal problems, while also taking a drug (aspirin) which clearly causes such problems. But theoretically that would be a workable compromise because a low enough dose of aspirin might not cause GI problems, but still give cardio-protective benefits," Shah said.

Dow Jones
April 28, 2000

DOES MERCK HAVE A PROBLEM WITH VIOXX?

BY REBECCA THOMAS

NEW YORK -(Dow Jones)- Are the feds coming after Merck (MRK)? Speculation ran rampant on Friday that government regulators are pondering the safety of the drug giant's arthritis drug Vioxx. Merck shares staggered as much as 5.6% lower on the news. But they bounced back a bit at the end of the day to close down 2.8% at $69.50.

What happened? Investors reacted to a Reuters report that Merck's hot-selling Vioxx may face intense scrutiny by the Food & Drug Administration. In a preliminary study conducted by Merck last month, patients taking the drug suffered more cases of heart damage than those on an alternative drug called naproxen.

Nonetheless, at least one analyst - and the company - said there's little to worry about. "This whole thing has been overblown and taken out of context," says Wall Street Journal All-Star analyst Jeff Chaffkin of PaineWebber. "We had this data over four weeks ago.this is nothing new."

While the belated sell-off in Merck's stock may have been unwarranted, it was certainly predictable given the news. Merck has a lot riding on the success of **Vioxx** and its other new products. "Vioxx is Merck's big home run," says David Saks, manager of the Medical Sciences Fund at Gruntal & Co. "It's their Mickey Mantle, their Babe Ruth."

Over the next two years, five of Merck's big sellers will lose patent protection, leaving them vulnerable to challenges from cheaper generics. In 1999, those five products generated $4.38 billion in U.S. sales and royalties. "**Vioxx** is critical to Merck's getting through the patent situation," says Larry Smith of Sutro & Co.

The drug was approved by the FDA in May to treat pain and osteoarthritis, the most common form of the disease. The study that triggered Friday's uproar was part of an effort by Merck to prove that Vioxx causes fewer ulcers and gastrointestinal side effects than an older, generic arthritis drug, naproxen. Ultimately, Merck also wants to win FDA approval to use the drug for a third ailment - rheumatoid arthritis. Some fretted that the questionable study would cloud those chances.

The study did, indeed, prove that Vioxx caused fewer gastrointestinal side-effects. But it also showed that patients using Vioxx had significantly more heart attacks and strokes than those on naproxen. What's not clear is whether Vioxx actually puts patients at higher risk of adverse events or whether naproxen confers heart-condition benefits.

Merck claims that naproxen probably protects patients against heart problems by preventing the accumulation of platelets that could form blood clots. Vioxx and other so-called Cox-II inhibitors do not block platelet aggregation and, therefore, should not be expected to reduce the incidence of cardiovascular problems. Moreover, a Merck spokeswoman pointed out that the company has conducted many other **Vioxx** studies where the drug was shown to be just as safe as alternative treatments when it comes to cardiovascular health.

FDA spokeswoman Susan Cruzan said the agency will examine the study when Merk submits it in the next few months. The FDA, she added, continues to believe that **Vioxx** is "safe and effective for its labeled uses."

The drug generated $472 million in sales last year and is one of the fastest growing new medicines ever. Analysts estimate it could have sales of $2 billion by 2002. If Merck wins approval to treat rheumatoid arthritis, that projection could climb by another $250 million, says Saks.

While Sutro's Smith thinks **Vioxx** is safe when taken in small dosages as required for osteoarthritis, he is concerned that the FDA will find that the higher 50 to 100 milligram dosages required in rheumatoid arthritis patients could cause safety problems. If side effects were shown to occur at small dosages, Merck would have a "huge problem" on its hands, he adds. For that reason, Smith downgraded the stock on Feb. 10 to Hold from Buy based on reduced enthusiasm for the drug.

Smith likes Pharmacia's (PHA) rival drug Celebrex better. That drug - which has been already been approved for rheumatoid arthritis and osteoarthritis, but not pain - does not have dosage issues, he says. It retains a very good safety profile when given at doses of over twice the recommended levels. Last year, Celebrex had sales of $1.5 billion.

But Merck's aggressive marketing strategy and Vioxx's indication for pain have helped **Vioxx** gain a significant market share of new prescriptions. In the most recent quarter, Celebrex sales rose nearly 7% to $534 million, while Vioxx sales jumped 40% to $370 million.

With Vioxx's future tied to the Feds, Merck's stock is bound to suffer from more indigestion, says Saks. "Everyone likes a clear window of growth." Smith is even more blunt: "Perceptions about the prospects for **Vioxx** are the single most important factor in Merck's stock price," he says. For now at least, investors concurred.

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Wall Street Journal
May 1, 2000

MERCK SHARES SINK ON WORRIES OVER VIOXX

BY GARDINER HARRIS, STAFF REPORTER OF THE WALL STREET JOURNAL

Belated concern over the footnotes to preliminary results of an arthritis-drug experiment sent Merck & Co.'s shares down Friday in yet another indication that, in this volatile market, traders need little pretext to dump or buy shares.

It isn't that Vioxx, the drug in question, isn't vitally important to Merck's future. It isn't that rare side effects can't scuttle important drugs. It is just that the numbers at the center of the concern are so early, so small and so open to dispute.

"I think it's a pig in a poke at this point. We can't conclude anything with these results," said Henry R. Black, an independent researcher and heart expert at Rush-Presbyterian-St. Lukes Medical Center in Chicago.

In New York Stock Exchange composite trading at 4 p.m. Friday, Merck was down $2, or 3%, at $69.50.

The root of the problem started in late March when Merck reported the preliminary results of a large test of Vioxx in rheumatoid arthritis patients. The study confirmed that Vioxx caused much fewer stomach and gut problems than a traditional pain and anti-inflammatory drug, naproxen. But in footnotes to the trial, Merck noted that 0.5% of those taking Vioxx had

heart attacks, compared with 0.1% who took naproxen-a statistically significant difference.

It was the first Vioxx experiment to show such an effect involving the heart. Merck researchers had several explanations for the finding but said there was no evidence that Vioxx was unsafe. Then resarchers from Pharmacia Inc. reported on April 17 the results of their study into the effectiveness of Celebrex, a competing arthritis drug. Pharmacia researchers emphasized they hadn't found any bad heart effects from Celebrex. That was followed by a story by Reuters late last week raising questions about the safety of Vioxx, which led to the hit to Merck's shares.

Launched just months apart, Celebrex and Vioxx act in similar ways by reducing inflammation, theoretically without harming the stomach and gut like traditional anti-inflammatories such as aspirin, naproxen and ibuprofen. While both drugs have been huge sellers, Merck and Pharmacia have been battling each other fiercely over which is better. With no data available directly comparing the drugs, the companies can't claim superiority of their drug, so such fighting has mostly been confined to whisper campaigns among company marketers and officials.

Launched first, Celebrex initially had a huge edge in sales over Vioxx. But Vioxx has been gaining steadily on its rival and has captured 48% of new prescriptions, according to IMS Health, a marketing-consulting firm.

Pharmacia seemed to have scored an important marketing coup when its trial showed no increase in heart attacks among Celebrex users. Celebrex must be safer than Vioxx, then, right?

Not exactly.

Unlike the patients in the Merck trial, many patients in the Celebrex trial were also taking aspirin — a drug long known to protect against heart attacks. Aspirin also causes ulcers. In fact, the presence of aspirin probably contributed to the fact that Pharmacia's trial failed to prove its primary goal — that Celebrex caused statistically fewer serious gastrointestinal events than Diclofenac or ibuprofen, a nonsteroidal anti-inflammatory.

Pharmacia's researchers pointed out that if they excluded aspirin users from the study, Celebrex proved safer to the stomach and gut than the other drugs-but that is the kind of statistical slicing that researchers and government regulators generally don't accept.

And when the Pharmacia data are examined more closely, it turns out that 0.5% of Celebrex users in the trial had heart attacks, compared with 0.3% of those taking Diclofenac and 0.5% for ibuprofen. Not to worry, Pharmacia researchers said, because while the level of heart attacks among Celebrex users was similar to that reported by Merck among Vioxx users in its trial, the difference in heartattack rates between Celebrex and Diclofenac wasn't statistically significant.

Confused? That's what happens when researchers bicker. In their calmer moments, Merck researchers say that, in high doses, Vioxx does cause blood pressures to increase in some patients-an effect not seen with Celebrex. Merck also says that their researchers have found that both Vioxx and Celebrex may constrain a natural drug in the body that slows clotting -not good for heart patients. Pharmacia's researchers say that any such effect is confined to Vioxx, not Celebrex.

While insisting its drug is perfectly safe, Merck's researchers suggest that patients at risk of heart disease might consider taking low-dose aspirin while taking Vioxx. But that would raise their risk of ulcers — the side-effect both Vioxx and Celebrex were designed to prevent.

Time and more data may sort out this argument. Then again, it may not. Since other anti-inflammatories may have effects on the heart, the best way to test the effect of Vioxx or Celebrex on the heart would be a comparison with a placebo. But since arthritis patients can't be allowed to suffer untreated, neither company's large experiments at this point include a placebo group. And directly testing Celebrex against Vioxx would likely be too great of a risk for either company.

So the argument, and the expensive marketing battle that goes with it, will likely continue while sales of the two drugs continue to climb, expected to exceed $3 billion together this year.

Reuters
May 21, 2000

VIOXX, CELEBREX AIM TO PROFIT FROM IMPROVED SAFETY LABELS

BY RANSDELL PIERSON

Two new rival arthritis drugs that have already become blockbusters, Merck & Co.'s Vioxx and Pharmacia Corp.'s Celebrex, aim to propel sales into higher orbit by convincing U.S. regulators in coming months that their medicines are far safer than standard treatments.

A key step in that campaign comes this week, when the firms will unveil data from separate clinical trials they say prove their medicines are overwhelmingly safer than older ulcer-causing arthritis remedies known as nonsteroidal anti-inflammatory drugs (NSAIDs).

The New Jersey drugmakers will describe the safety trials at the annual Digestive Disease Week meeting being held in San Diego. By mid-year, the companies then plan to forward the data to the U.S. Food and Drug Administration, asking the agency to certify their medicines as members of a separate and safer class.

"Vioxx and Celebrex are expensive, so many managed care companies now refuse to pay for them unless patients have previously failed on cheaper, older medicines," said Peter Wen, co-portfolio manager of the Warburg Pincus Global Health Sciences Fund.

"But if the FDA agrees that Vioxx and Celebrex are indeed safer than NSAIDs and allows the drugs to say so on their labels, more insurers presumably would allow

them on their formularies," or lists of approved medications, Wen added.

BOASTING RIGHTS FOR DIRECT-TO-CONSUMER ADS

A superior safety label would also allow Vioxx and Celebrex, for the first time, to boast in direct-to-consumer television and print advertisements that they are safer than NSAIDs such as aspirin, naproxen, diclofenac and ibuprofen, said Carl Seiden, an analyst with J.P. Morgan.

"If things go well, a year from now they can begin pitching their more-aggressive ads to consumers" and steal bigger chunks of business from NSAIDs, which now account annually for about 80 million U.S. prescriptions, Seiden said.

The FDA last year approved Vioxx (rofecoxib) and Celebrex (celecoxib) for treatment of osteoarthritis - the most common form of arthritis affecting about 21 million Americans in which joints are damaged by normal wear and tear.

In addition, Vioxx was approved for treatment of short-term pain, such as after surgery or dental work, while Celebrex was cleared for treatment of rheumatoid arthritis - the crippling less-common form of arthritis affecting 2.1 million Americans in which the body's immune system attacks joints.

Merck plans late this year to also seek marketing approval of Vioxx for rheumatoid arthritis, based on other safety and efficacy trials.

Celebrex, launched in January, 1999, garnered global sales of $1.5 billion the same year. Vioxx, which hit

drugstores four months later, had 1999 global sales of $472 million.

They are the first in a new type of pain and arthritis medicines that work by selectively blocking the so-called Cox-2 enzyme which has been linked to inflammation. Thus, they have been nicknamed "Cox-2 inhibitors."

Standard NSAIDs also block Cox-2, but are believed to cause a much higher number of ulcers and gastrointestinal problems because they also block the related Cox-1 enzyme, which protects the stomach lining. In fact, over 16,000 U.S. deaths each year are blamed on NSAIDs.

DRUGS NOW LUMPED INTO OLDER NSAIDS CLASS

Nevertheless, when the FDA approved Vioxx and Celebrex last year on the basis of placebo-controlled trials, it lumped them into the old NSAIDs class, pending completion of post-marketing safety trials showing they are indeed gentler on the gastrointestinal tract than leading NSAIDs.

Results of Pharmacia's 13-month "CLASS" trial, involving 5,800 patients with osteoarthritis and 2,200 with rheumatoid arthritis, will be presented Monday evening at the San Diego meeting. It will compare long-term safety of Celebrex with diclofenac and ibuprofen.

Merck's "VIGOR" trial, of 8,000 patients with rheumatoid arthritis, will be presented Wednesday afternoon. It compares the incidence of serious gastrointestinal events among Vioxx users with those in naproxen users over an average period of 9 months.

Both companies have previously given brief preliminary summaries of their safety trial results.

Pharmacia said last month that patients taking 800 milligrams daily of Celebrex, four times its recommended dose for osteoarthritis and twice its recommended daily dose for rheumatoid arthritis, had statistically meaningful fewer incidents of symptomatic ulcers and ulcer complications than the combined group of patients taking standard daily doses of ibuprofen and diclofenac.

CELEBREX TRIAL SHOWS CONFLICTING RESULTS

Specifically, 2.1 percent of those taking Celebrex had ulcers and complications, compared with 3.6 percent of the NSAID group, Pharmacia officials said late Sunday.

When considering ulcer complications alone, without also including symptomatic ulcers, the incidence among those taking Celebrex was 0.8 percent, versus 1.5 percent for those taking NSAIDs - a positive trend that failed to achieve statistical significance.

Pharmacia said Celebrex apparently failed that part of the study because about 22 percent of patients in the overall CLASS trial were also taking aspirin, typically in low doses, to protect against heart attacks and other cardiovascular problems.

Excluding the aspirin group, Pharmacia senior researcher Steven Geis said the rate of ulcer complications for Celebrex was 0.4 percent compared with 1.3 percent in the NSAIDs group - a reduction which he said was statistically significant.

"That's the purest view of what Celebrex really does. When you take away the influence of aspirin, you clearly see a 3-fold difference between Celebrex and the NSAIDs," Geis said in an interview.

VIOXX STUDY ALSO GIVES MIXED MESSAGE

Merck in late March said a preliminary analysis of its VIGOUR trial showed that rheumatoid arthritis patients treated with a daily 50 mg dose of Vioxx had a significantly relevant reduced incidence of serious gastrointestinal problems than those taking naproxen.

But Merck stirred controversy by disclosing that only one-fifth as many patients taking naproxen had heart attacks as those taking Vioxx (0.1 percent versus 0.5 percent).

Merck attributed the finding to naproxen's presumed ability to prevent platelets from clumping together to form blood clots, saying there was no reason to believe that Vioxx itself caused heart attacks.

In fact, Merck said there was no statistical difference in heart attacks between patients who took Vioxx and those who took other NSAIDs in previous clinical trials involving treatment of osteoarthritis and acute pain.

"The FDA has a huge database from Merck, of 10,000 patients where there is no increased incidence of heart attacks" with Vioxx, Dr. Eve Slater, Merck's senior vice president of clinical and regulatory development, said in an interview.

"The FDA is not concerned about this issue to the best of my knowledge, to the extent they have seen the data we have," Slater said.

J.P. Morgan's Seiden speculated the FDA will allow Celebrex and Vioxx to put stronger safety claims on their labels because of very favourable overall trends in the CLASS and VIGOUR trials. But he predicted neither drug would be allowed to shake off its NSAID tag and become members of a separate "Cox-2 inhibitor" class, in part because of the partial failures in both trials.

"I think the Celebrex issue will be easier to deal with because although the total Celebrex group failed to show a lower rate of ulcer complications, there was clear statistical significance in those who took no aspirin," Seiden said.

By contrast, he said Merck has offered only a credible theory why fewer patients taking naproxen had heart attacks than those taking Vioxx in the VIGOUR trial.

"But it's only a theory. There's nothing in the trial to prove the supposedly beneficial effects of naproxen," Seiden said.

Another New York analyst, who asked to remain anonymous, said the FDA will be faced with a tough decision. "How can they keep one drug an NSAID and let the other one go free when both drugs had conflicting results? The Solomon-like decision would probably be for the FDA to do nothing and just keep them both as NSAIDs."

The FDA could not be reached for comment.

Reuters
May 24, 2000

VIOXX SHOWN SAFER ON GI TRACT THAN OLDER DRUG

Merck & Co. Inc. said on Wednesday that rheumatoid arthritis patients taking its drug Vioxx suffered less than half the incidence of ulcers and serious gastrointestinal problems of those taking a popular older drug, naproxen, in a large safety trial.

Data from the 8,000-patient study, called VIGOUR, were presented in San Diego at Digestive Disease Week, the nation's largest meeting of gastrointestinal (GI) specialists.

"Results on gastrointestinal safety of Vioxx were very impressive," said PaineWebber drug analyst Jeffrey Chaffkin, who noted that Vioxx was developed to offer equivalent effectiveness of older arthritis drugs but with milder GI side effects.

Merck said its blockbuster Vioxx was well-tolerated in the study, although patients taking it had more heart attacks than those taking naproxen during the 13-month worldwide trial.

Merck attributed naproxen's better results in heart attacks to the older drug's presumed ability to prevent blood platelets from clumping together to form blood clots. It said no difference in heart attack incidents was seen in earlier trials that compared Vioxx to other standard arthritis drugs.

Moreover, Merck said there was no significant difference in heart attacks between the Vioxx and naproxen groups in VIGOR, when excluding

consideration of the 4 percent of the total study group that had previously suffered heart attacks, strokes, other cardiovascular incidents or had angioplasty or more serious medical interventions.

U.S. regulators approved Vioxx for acute pain and osteoarthritis last year on the basis of studies comparing it to placebos. Osteoarthritis is the most common form of arthritis and causes breakdown of the affected joints.

After launching the drug, Merck conducted the VIGOR trial among rheumatoid arthritis patients to see whether Vioxx was indeed safer than traditional arthritis drugs.

Rheumatoid arthritis is the less common form of arthritis, in which the body's immune system attacks the joints. Vioxx is not currently approved for treating rheumatoid arthritis, but Merck has completed Phase III trials of the drug for the autoimmune disorder and plans by the end of the year to seek U.S. marketing approval to treat the condition.

VIGOR pitted Vioxx against naproxen, one of the most commonly used members of the family of traditional nonsteroidal anti-inflammatory drugs (NSAIDs), which also includes aspirin.

Patients were divided into two groups, one of which took a daily 50 milligram dose of Vioxx, two to four times higher than the standard osteoarthritis dose of Vioxx. Others took naproxen in a 500 milligram dose twice a day, which is its standard daily regimen for treating rheumatoid arthritis.

Vioxx reduced the risk by 54 percent of symptomatic ulcers and complicated GI events, including ulcers, perforations, obstructions and bleeding in the upper GI

tract, compared to the naproxen group, Merck said. The difference in side effects was statistically significant.

"The rate of these events was 4.5 percent per year among patients taking naproxen, compared to 2.1 percent per year among patients taking Vioxx," Merck said in a prepared release.

When considering only complicated GI events, but not symptomatic ulcers, Vioxx reduced the risk by 57 percent, compared to naproxen, a difference which was also statistically relevant.

"The rate of these events was 1.4 percent per year among patients taking naproxen, compared to 0.6 percent per year among patients taking Vioxx," Merck said.

"In this study, Vioxx also reduced bleeding from the GI tract by 62 percent" compared to naproxen, Merck said.

There was no difference in cardiovascular mortality and incidence of strokes in the two VIGOR groups, Merck said. But it added that "significantly fewer heart attacks were seen in patients taking naproxen (0.1 percent) compared to the group taking Vioxx (0.4 percent) in this study."

"The reduction in heart attacks is consistent with naproxen's ability to block platelet aggregation," Merck said. It said naproxen's ability to prevent platelet-clumping was similar to that of low-dose aspirin, which is taken by many patients with cardiovascular problems to prevent heart attack and stroke.

No patients taking aspirin were admitted in the VIGOUR trial. But Merck said the 4 percent of the total study group who had previous cardiovascular incidents

and medical procedures would have been appropriate candidates for taking cardio-protective doses of low-dose aspirin.

Among the remaining 96 percent of patients, Merck said there was no significant difference in heart attack rates between the Vioxx and naproxen groups - 0.1 percent for those on naproxen and 0.2 percent for patients on Vioxx.

"When you exclude consideration of the 4 percent who have had previous cardiovascular incidents, the difference in heart attacks between the Vioxx and naproxen patients are less a problem than previously speculated. I don't think it's an issue at all," said Tony Butler, a Lehman Brothers analyst.

About 46 percent of the total VIGOR group had what Nerck termed a previous history of cardiovascular disease, which included people with hypertension.

Some other analysts, including Brown Brothers Harriman's Mike Krensavage, said the heart-attack difference remained very much an issue, particularly given the demographics of the population taking Vioxx.

"The average age of patients in the study was 58, and 46 percent had some history of cardiovascular disease, so the targeted population is vulnerable to cardiovascular problems. Heart attacks are serious events. There's no way to say, 'This is nothing.' These data should encourage regulators to take a closer look at this drug," Krensavage said.

Although the trial was meant to test for safety, Merck said both Vioxx and naproxen reduced the severity of rheumatoid arthritis equally in the VIGOUR trial.

Merck has said it plans to submit the VIGOUR data to U.S. regulators within the next few months, in hopes the GI safety data can be added to the Vioxx insert label.

Vioxx is designed to provide similar relief for arthritis and pain as traditional NSAIDs, but with less risk of causing ulcers and gastrointestinal damage.

It and Pharmacia Corp.'s drug Celebrex selectively block the Cox-2 enzyme linked to inflammation. Older arthritis drugs like naproxen also block the enzyme, but are believed to cause more ulcers and GI problems by also blocking the related Cox-1 enzyme that protects the stomach lining.

Merck rose 7/8 to 74-11/16 on the New York Stock Exchange.

Bloomberg News
February 7, 2001

MERCK'S VIOXX SAFETY WARNING SHOULD REMAIN, FDA REVIEW SAYS

Merck & Co. shouldn't be allowed to remove a broad warning of the risk of stomach problems from the label of its blockbuster painkiller Vioxx, U.S. Food and Drug Administration medical officers have recommended.

Agency reviewers made a similar recommendation for Vioxx's competitor, Pharmacia Corp.'s Celebrex, which is being considered today by an FDA advisory panel. The panel will consider Vioxx's safety tomorrow.

All painkillers classified as non-steroidal anti-inflammatory drugs, or NSAIDs, carry a warning of stomach bleeding. Both Merck and Pharmacia have asked the agency to remove that warning on their drugs, giving them a significant advantage over older, cheaper painkillers. Vioxx and Celebrex can cost $2 a pill.

The FDA review prepared for tomorrow's meeting, said Vioxx was less likely than an older, cheaper drug called naproxen to cause ulcers or stomach bleeding, though that advantage wasn't great enough to merit a change to the label.

"The NSAID-class (gastrointestinal) warning should not be removed from the Vioxx label," concluded Maria Lourdes Villabla and Lawrence Goldkind, who reviewed the Merck data for the FDA.

In addition, the reviewers pointed to an increase in risk of heart problems such as heart attacks in patients taking Vioxx compared to patients taking naproxen. Though Merck said the difference could be explained by

beneficial effects of naproxen, and not harmful effects of Vioxx, the reviewers recommended data on the heart problems should be added to the drug's label.

Bloomberg
February 8, 2001

MERCK'S VIOXX UNLIKELY TO CAUSE HEART PROBLEMS, FDA PANEL FINDS

BYLINE: BRIAN REID

Merck & Co.'s Vioxx painkiller isn't likely to cause cardiovascular problems, an U.S. government advisory panel said, though panelists called for more study to see if there is any link between the drug and heart problems.

The U.S. Food and Drug Administration advisory panel reviewed research showing patients taking Vioxx have higher rates of heart attacks than those taken naproxen, an older, cheaper painkiller. The difference could be the result of a cardiovascular benefit to taking naproxen, not a risk to taking Vioxx, the panel found.

The finding makes it less likely that Vioxx's label will carry a significant warning of heart attacks or other cardiovascular problems, which would limit the use of the drug in the highly competitive market that Vioxx shares with Pharmacia Corp.'s Celebrex.

"This provides some reassurance that what we see, in effect, is a protective effect of naproxen," said Steven Nissen, a panel member and a cardiologist at the Ohio State University. Till Nissen endorsed additional study of the effect of both Vioxx and naproxen.

Some studies suggest that naproxen may help keep the blood clear of clots, much like aspirin, thereby reducing the risk that a clost will cause a heart attack or a stroke, panelists said. Vioxx, designed to have no effect on clotting, would therefore appear to have a

higher risk of heart problems when compared to naproxen.

Some panelists suggested that doctors and consumers be made aware that there is no protective effect on the heart associated with Vioxx, though others suggested the drug carry more specific information about the increase in risk over naproxen.

Merck shares rose 65 cents to $82.50 in midafternoon trading.

The panel also heard data that said Vioxx was significantly less likely to cause stomach bleeding or ulcers that naproxen. Merck is seeking a change to the drug's label to suggest it is safer than older painkillers.

Still, the FDA staff recommended in documents to the panel that the standard warning attached to all-non-steriodal anti-inflammatory painkillers remain on the Vioxx label.

Yesterday, the same panel concluded a similar study of Celebrex hadn't been shown to be significantly safer than two other older painkillers, ibuprofen and dioclofenac.

Dow Jones & Reuters
February 8, 2001

MERCK STUDY SHOWS VIOXX SAFER ON STOMACH - FDA PANEL

Merck and Co.'s popular arthritis drug Vioxx, in a company study, appeared safer on the stomach than naproxen, one of a group of widely used pain medicines, a U.S. advisory panel said Thursday.

The Food and Drug Administration (FDA) committee urged the agency to include that information on the label for the prescription drug. The FDA usually follows the advice of its panel.

The committee also expressed concern, however, that more Vioxx patients in Merck's trial suffered heart attacks and other cardiovascular events than patients taking naproxen. The panel recommended that the Vioxx label carry that information, even though members were not sure that Vioxx was responsible for the adverse effects.

PR Newswire
February 8, 2001

FDA ARTHRITIS ADVISORY COMMITTEE REVIEWS MERCK'S APPLICATION FOR REVISED LABELING FOR VIOXX® BASED ON VIOXX GASTROINTESTINAL OUTCOMES STUDY

The Arthritis Advisory Committee of the Food and Drug Administration today reviewed Merck & Co., Inc.'s application for changes to the prescribing information for Vioxx(R) (rofecoxib), Merck's medicine for osteoarthritis and acute pain, to reflect results from the Vioxx Gastrointestinal Outcomes Research (VIGOR) study.

The Advisory Committee agreed with Merck and the FDA that results from the study should be included in the labeling for Vioxx. The FDA is not obligated to follow the advice of the Advisory Committee, but usually does. The FDA noted that it will consider all available information, including the information reported and advice received at today's Advisory Committee meeting, before any final decisions are made on Merck's application and other issues discussed by the Committee.

"Merck is confident that the data presented today support the excellent safety profile of Vioxx, and we look forward to further discussions with the FDA to complete the review of our application to modify the labeling for Vioxx," said Eve Slater, M.D., senior vice president, Clinical and Regulatory Development, Merck Research Laboratories.

Vioxx was approved by the FDA in May 1999 to treat osteoarthritis and acute pain. The prescribing information for Vioxx currently contains the standard

NSAID Warning about GI side effects. Merck's application to the FDA was based on the 8,000-patient VIGOR study, which evaluated the GI profile of Vioxx 50 mg compared to the non-selective NSAID naproxen, and on other studies with Vioxx.

In VIGOR, Vioxx 50 mg, a dose two-times the highest chronic dose approved for osteoarthritis, significantly reduced serious GI side effects by half compared to a commonly used dose of naproxen (1,000 mg) in rheumatoid arthritis patients. The Committee recommended that these results be included in the labeling. Vioxx is not indicated for rheumatoid arthritis.

Although the VIGOR study was a GI outcomes study and was not designed to show differences in cardiovascular effects, significantly fewer heart attacks were observed in patients taking naproxen (0.1 percent) compared to the group taking Vioxx 50 mg (0.5 percent) in this study. There was no difference in cardiovascular mortality between the groups treated with Vioxx or naproxen. Patients taking aspirin did not participate in VIGOR.

In extensive discussions, the Advisory Committee explored this finding, other studies of Vioxx and possible explanations for this result in VIGOR. In the completed osteoarthritis trials and on-going clinical trials with Vioxx 12.5 mg, 25 mg and 50 mg in 30,000 patients, there was no difference in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx, other NSAIDs and placebo.

Merck scientists said the VIGOR finding is consistent with naproxen's ability to block platelet aggregation by inhibiting COX-1 like aspirin, which is used to prevent second cardiac events in patients with a history of heart

attack, stroke or other cardiac events. This is the first time this effect of naproxen on cardiovascular events has been observed in a clinical study. Other explanations were advanced by the FDA reviewer and were discussed with the Advisory Committee. The Committee recommended that the data on cardiovascular events in VIGOR be included in the labeling for Vioxx.

In addition, the Committee agreed that the prescribing information for both Vioxx and Celebrex(R) (celecoxib) should reflect the fact that neither of these selective NSAIDs confer cardioprotective benefits and are not a substitute for low-dose aspirin. The Committee also recommended that other studies be conducted to further explore the safety of concomitant use of selective NSAIDs and low-dose aspirin.

Important information about Vioxx Vioxx is approved in the United States for the relief of the signs and symptoms of osteoarthritis, management of acute pain in adults and treatment of menstrual pain. The recommended starting dose of Vioxx for the treatment of osteoarthritis is 12.5 mg once daily. Some patients may receive additional benefit by increasing the dose to 25 mg once daily, the maximum recommended dose for osteoarthritis.

Vioxx does not block platelet aggregation and should not be used as a substitute for aspirin to prevent cardiac events. Vioxx does not interfere with the ability of low-dose aspirin to block platelet aggregation. Administration of low-dose aspirin with Vioxx may result in an increased rate of GI ulcers or other complications compared to use of Vioxx alone.

In rare cases, serious stomach problems, such as bleeding, can occur without warning symptoms. People

who have had an allergic reaction, such as asthma, to Vioxx, aspirin or other arthritis medicines should not take Vioxx. People who have liver or kidney problems, or are pregnant, should tell their doctors. Also, Vioxx should not be used by women in late pregnancy. Common side effects reported in other clinical trials with Vioxx were upper-respiratory infection, diarrhea, nausea and high blood pressure.

Merck & Co., Inc. (NYSE: MRK) is a leading research-driven pharmaceutical products and services company. Merck discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health, directly and through its joint ventures. Merck-Medco Managed Care manages pharmacy benefits for employers, insurers and other plan sponsors, encouraging the appropriate use of medicines and providing disease management programs. Through these complementary capabilities, Merck works to improve quality of life and contain overall health-care costs.

Full prescribing information for Vioxx(R) follows and is also available by calling 1-800-753-0352, ext. 726.

Vioxx(R) is the Merck registered trademark for rofecoxib.

Celebrex(R) is a registered trademark of Pharmacia Corporation.

VIOXX(R)

(rofecoxib tablets and oral suspension)

DESCRIPTION

VIOXX* (rofecoxib) is described chemically as 4-[4-(methylsulfonyl)phenyl]-3-phenyl-2(5H)-furanone. It has the following chemical structure:

MOLECULE HERE

Rofecoxib is a white to off-white to light yellow powder. It is sparingly soluble in acetone, slightly soluble in methanol and isopropyl acetate, very slightly soluble in ethanol, practically insoluble in octanol, and insoluble in water. The empirical formula for rofecoxib is C17H14O4S, and the molecular weight is 314.36.

Each tablet of VIOXX for oral administration contains either 12.5 mg, 25 mg, or 50 mg of rofecoxib and the following inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, lactose, magnesium stearate, microcrystalline cellulose, and yellow ferric oxide. The 50 mg tablets also contain red ferric oxide.

Bloomberg
February 8, 2001

MERCK DRUG SHOULD NOTE HEART RISK, STOMACH BENEFIT, PANEL SAYS

Merck & Co. should update the label on its Vioxx painkiller to point out greater risk to the heart, compared to an older drug, as it boasts of less distress to the stomach, a government advisory panel said.

The U.S. Food and Drug Administration advisory panel suggested that the Vioxx label highlight research showing patients taking the drug have higher rates of heart attacks than those taken naproxen, an older, cheaper painkiller. The panel also suggested language to note fewer stomach problems in Vioxx patients compared to naproxen patients.

Merck and Pharmacia Corp., maker of a similar drug called Celebrex, were seeking label changes to let them claim safety advantages over older painkillers and increase prescriptions for medicines that are among the most successful ever introduced, with sales this year of more than $2 billion each. The FDA panel's recommendations won't give an edge to either drug, analysts said.

"Is this going to meaningfully change clinical practice? Probably not. This is not a major overhaul of the label," said Robert Hazlett, an analyst at Robertson Stephens.

Vioxx and Celebrex, like all painkillers classified as nonsteroidal anti-inflammatory drugs, or NSAIDs, carry a warning of stomach bleeding. Pharmacia and Merck submitted studies to support their argument that their

painkillers are safer than older, cheaper NSAIDS such as ibuprofen and naproxen.

While the panel didn't recommend removing the stomach bleeding warning, it backed Merck's request to highlight research showing less likelihood of gastrointestinal problems among Vioxx patients than those on naproxen.

Yesterday, the same panel concluded Pharmacia's study of Celebrex hadn't been shown the drug to be significantly safer than two other older painkillers, ibuprofen and diclofenac.

Heart Risk

Unlike Pharmacia, Merck also had to convince the panel that its drug wasn't responsible for raising the risk of heart attack or stroke.

Differences in cardiac risk between Vioxx and naproxen appeared to result from a beneficial effect of naproxen, not a danger from Vioxx, said Nigel Harris, the panel's chairman and the dean of the department of internal medicine at Morehouse School of Medicine.

Some studies suggest that naproxen may help keep the blood clear of clots, much like aspirin, thereby reducing the risk that a clot will cause a heart attack or a stroke, panelists said.Vioxx, designed to have no effect on clotting, would therefore appear to have a higher risk of heart problems when compared to naproxen.

"This provides some reassurance that what we see, in effect, is a protective effect of naproxen," said Steven Nissen, a panel member and a cardiologist at the Ohio State University. Still, Nissen endorsed additional study of the effect of both Vioxx and naproxen.

Merck shares rose $1.12 to $82.97. Pharmacia shares fell $3.13 to $53.

Vioxx Safety

The panel agreed with data that said Vioxx was significantly less likely to cause stomach bleeding or ulcers than naproxen.

Harris said that any changes in the label concerning gastrointestinal safety would have to be very specific, noting that Merck has shown an advantage only in comparison to naproxen in a specific group of patients with rheumatoid arthritis.

"There is less gastrointestinal toxicity in this drug, with this particular comparator in this patient population," said Harris.

Associated Press
February 8, 2001

SCIENTISTS: ARTHRITIS PAINKILLER VIOXX CAUSES FEWER ULCERS THAN NAPROXEN

The arthritis drug Vioxx appears to cause fewer ulcers than the older painkiller naproxen and its label should say so, the government's scientific advisers decided Thursday in a boon for maker Merck & Co.

But the panel didn't have all good news for Merck: Vioxx should retain its strong warning that it can cause ulcers just like some other older, cheaper painkillers - and doctors and patients should be warned that it might carry a heart risk, too.

The recommendation comes as Vioxx and competitor Celebrex, two popular arthritis painkillers, jockey for sales.

Merck and Celebrex maker Pharmacia Corp. want the Food and Drug Administration to quit making the products bear the same warning as older painkillers that users risk developing ulcers, even life-threatening gastrointestinal bleeding. Celebrex and Vioxx work slightly differently than older painkillers, and thus proponents hoped they would prove gentler on the stomach. But on Wednesday, the same FDA advisory panel ruled there's no proof Celebrex is gentler on the stomach.

Then Thursday, the panel examined Merck's 8,000-patient study comparing Vioxx and naproxen - and said Vioxx did cause somewhat fewer ulcers. But the panel said the drug's label should reflect both that one study and retain its broad warning that Vioxx still can cause ulcers.

Also, the panel said patients and doctors must be warned that in the study, Vioxx patients had twice the risk of heart attacks or other cardiovascular side effects as naproxen users.

Why? No one's sure. Partly, naproxen may thin the blood, much like the aspirin used by heart patients to prevent blood clots, and thus using Vioxx instead deprived patients of the other drug's side benefit. However, some critics say Vioxx and Celebrex themselves may increase the risk of blood clots. FDA's advisers concluded more research is needed but that meanwhile, Vioxx's label should warn of the concern.

The FDA isn't bound by its advisers' recommendations but typically follows them.

On the Net: The FDA: http://www.fda.gov

Reuters
February 9, 2001

U.S. PANEL URGES LABEL CHANGES FOR MERCK'S VIOXX

BY LISA RICHWINE

A U.S. advisory panel on Thursday urged regulators to modify the label on Merck and Co.'s Vioxx to say that one study found the popular arthritis drug gentler on the stomach than another painkiller.

The panel also said, however, that prescribing information should note that study results raised the issue of whether Vioxx patients faced higher risks of heart problems, and they urged further study to try and answer that question.

Vioxx is battling with Pharmacia Corp.'sCelebrex in the multibillion dollar anti-arthritis market, and both companies are asking regulators to change their products' labels to give the firms a marketing edge.

Industry analysts said after the meeting it did not look likely either company would gain a major advantage.

Both drugs were designed to be safer than other, less expensive painkillers called nonsteroidal anti-inflammatory drugs, or NSAIDs. NSAIDs such as aspirin and ibuprofen are blamed for 16,500 U.S. deaths each year from stomach bleeding and related complications.

With Vioxx, the Food and Drug Administration (FDA) advisory committee stressed that they could only deduce a benefit for the type of people in Merck's 8,000-patient study. The trial compared Vioxx and pain

medicine naproxen in rheumatoid arthritis patients who were not allowed to take aspirin to protect against heart problems.

Vioxx is approved to treat osteoarthritis and not rheumatoid arthritis, although Merck has said it aims to have the drug approved for that condition.

"The sense is the label should be modified at least to . . . reflect increased (gastrointestinal) protection for these patients in this particular trial," Acting Panel Chairman E. Nigel Harris told reporters.

ISSUE GOES TO FDA

The FDA will decide whether to update the labels for Vioxx or Celebrex, which Pfizer Inc. co-markets. On Wednesday, the same FDA panel said Pharmacia's data did not prove that Celebrex was less harmful to the stomach than two other drugs.

The FDA typically follows its panels' advice, but members did not give specific ideas on what language to use.

The panel was concerned that more Vioxx patients in Merck's trial had heart attacks and other cardiovascular problems than patients taking naproxen. But members said it was possible that Vioxx did no harm and that naproxen protected the heart, as Merck argued.

Still, the committee felt the information was important to convey to doctors, especially because many arthritis patients are elderly and at risk for heart problems.

"I don't think it rises to a warning.... Based on what we've seen so far, there is a lack of cardioprotection" for Vioxx, Harris said.

Eve Slater, Merck's senior vice president for clinical and regulatory development, said she felt the panel's overall recommendations were "great" and that Merck believes "Vioxx is neutral to cardiovascular events."

Celebrex and Vioxx debuted on the U.S. market about two years ago, and combined sales rocketed to nearly $5 billion last year, making their launches two of the most successful ever.

MEETINGS 'A WASH' FOR BOTH DRUGS

Robertson Stephens drug analyst Robert Hazlett said he believed the presentations to the FDA panel were "slightly favorable" to the two drugs but failed in their ambitious efforts to show strong advantages over the cheaper and older standard NSAID therapies.

"There were expectations the drugs would show significant improvements over NSAIDs, and it's pretty clear that wasn't the case," he said.

Based on the findings, the FDA is unlikely to allow either Vioxx or Celebrex to make general claims of greater safety than NSAIDs, but merely respective advantages over different individual NSAIDs, he said.

"At the end of the day, the presentations showed a modest improvement and probably a 'push' for both drugs," he said.

Deutsche Banc Alex. Brown analyst Barbara Ryan said she believed the presentations from both firms were "a wash."

She said the FDA is likely to allow Celebrex to claim on its label better safety than ibuprofen and Vioxx to claim better safety than naproxen - offset by a warning for both drugs that they do not have the cardioprotective advantages of some NSAIDs.

Vioxx and Celebrex are part of a class known as COX-2 inhibitors. Developers hoped they would relieve pain as well as NSAIDs with less risk of ulcers, stomach bleeding or other dangerous gastrointestinal side effects. Such complications occur in 2 to 4 percent of patients who take NSAIDs for a year.

NSAIDs target an enzyme called cyclooxygenase, or COX, which has two forms, COX-1 and COX-2. Experts believe COX-2 plays a role in pain and inflammation while COX-1 is involved in protecting the stomach lining.

While most NSAIDs inhibit both, Celebrex and Vioxx work against only COX-2. The theory is that blocking only COX-2 leaves COX-1 free to protect and heal the stomach, thereby leading to fewer side effects than traditional NSAIDs.

COX-2 inhibitors cost about $2 per day, compared with pennies per day for other NSAIDs.

On the New York Stock Exchange, Pharmacia closed down $3.13, or 5.6 percent, to $53.00, while Pfizer edged up 25 cents to $44.75. Merck gained $1.12 to $82.97, also on the Big Board.

Ryan said she believed Pharmacia's stock fell sharply late Thursday "over concern that Merck might be able to make positive claims that Pharmacia won't be able to make. But I don't think that will be the case."

(With additional reporting by Ransdell Pierson in New York).

Star-Ledger (Newark, New Jersey)
February 9, 2001

FEDERAL PANEL SUGGESTS MORE STUDIES OF VIOXX

BYLINE: ED SILVERMAN, STAR-LEDGER STAFF

A federal advisory panel yesterday determined Merck & Co.'s best-selling painkiller, Vioxx, isn't likely to cause heart problems, but urged regulators to consider additional studies to clarify the issue.

In reaching its decision, the panel reviewed data showing patients taking Vioxx had more heart attacks than those taking naproxen, an older and cheaper painkiller. But it was unclear if Vioxx caused a risk or if naproxen offers some type of cardiovascular benefit.

Merck shares rose $1.12 to $82.97 yesterday. The stock is down 11 percent this year.

It's not clear, though, whether the Food and Drug Administration will require Vioxx patient information to carry a warning of heart attacks, a red flag that would limit its use and, therefore, provide an edge to Celebrex, a rival pill sold by Pharmacia Corp.

At the same time, the panel found that Vioxx appears easier on the stomach than naproxen. Two days ago, the same panel found that Celebrex wasn't significantly safer than two other painkillers from the older group of non- steroidal anti-inflammatories, or NSAIDs.

"I view the outcome for Merck as somewhat neutral," said Jeffrey Chaffkin, an analyst at UBS Warburg Paine Webber, who tracks the drug industry. "Merck will get a slightly better label on gastrointestinal issues, but the FDA might highlight a cardiovascular risk.

"So it's really not a major victory at all for Merck. Of course, we don't yet know what the FDA will do. They often follow the recommendations from their panels, but you never know."

USA TODAY
February 9, 2001

VIOXX MIGHT RAISE HEART RISK

BYLINE: RITA RUBIN

Arthritis patients who take Vioxx because they think it's safer on the stomach should know that the blockbuster drug might increase their risk of suffering a heart attack, an FDA advisory committee concluded Thursday.

"It would be indefensible not to share this information with the public," says David Wofsy, a University of California at San Francisco rheumatologist who served as a consultant to the committee. The FDA usually follows its advisory committee's recommendations.

Merck had come before the advisory committee to make the case that Vioxx should not have to carry the same warning about gastrointestinal (GI) complications as other non-steroidal anti-inflammatory drugs, or NSAIDs. Vioxx and its rival, Celebrex, came on the market in 1999 and had two of the most successful launches of any drug, with sales totaling more than $ 3 billion last year.

Vioxx and Celebrex had gained a reputation as "super aspirins" because they were thought to be safer on the stomach than aspirin and other NSAIDs.

Merck conducted a study of more than 8,000 patients comparing Vioxx with naproxen, sold as Aleve. The study, dubbed VIGOR, found that Vioxx patients experienced significantly fewer serious ulcers than those on naproxen. On the basis of that study, the advisory

committee recommended that Merck be allowed to claim only that Vioxx is safer than naproxen in patients who are not also taking low-dose aspirin to protect against heart attacks. (The Vigor study excluded patients who also were taking aspirin.)

However, Vigor also found that patients on Vioxx were more likely to suffer heart attacks and other cardiovascular complications than those on naproxen. The advisory committee recommended that this finding be noted on Vioxx's label.

On Wednesday, the advisory committee concluded that Pharmacia, the maker of Celebrex, had failed to prove that its drug was safer on the stomach. However, Pharmacia's study included patients taking aspirin, which might have erased Celebrex's GI safety advantage. Their study also compared Celebrex to two NSAIDs, not just one as Merck had done.

New York Times
May 22, 2001

DOUBTS ARE RAISED ON THE SAFETY OF 2 POPULAR ARTHRITIS DRUGS

BYLINE: MELODY PETERSEN

Doctors are beginning to worry that Vioxx and Celebrex, two wildly popular arthritis drugs, may not be as safe as they were initially believed to be.

Research presented to the Food and Drug Administration earlier this year showed that patients taking Vioxx, a Merck & Company drug, had a higher, but still relatively low, risk of heart attacks than patients taking an older pain reliever. The study received little public attention at the time, but the F.D.A. is considering whether to add information on possible cardiovascular side effects to both drugs' labels.

Now Wall Street is becoming aware of the possible problems, with at least one analyst warning that the problem could particularly affect Merck.

The two drugs, which cause fewer ulcers than many other pain relievers, are among the best-selling medicines in the world. And both Pharmacia, which makes Celebrex, and Merck are heavily dependent on the drugs for the sales growth that Wall Street expects.

Celebrex is Pharmacia's biggest-selling drug, generating sales of $2.3 billion in the 12 months ending in March, according to IMS Health. Pfizer co-markets Celebrex with Pharmacia. Merck sold $1.7 billion of Vioxx in the same period, making it the company's second-biggest drug behind the cholesterol medicine Zocor.

Millions of Americans have tried Vioxx or Celebrex, many of them prompted to request them from doctors after seeing television advertisements paid for by the two companies, which are locked in a fierce marketing battle.

While the data is still limited, a large study sponsored by Merck last year showed that patients taking Vioxx had four times the risk of heart attacks of patients taking another pain reliever, naproxen, which is sold both generically and under the brand names Naprosyn or Aleve. The risk, which appears to increase over time, was still low, however, at about 4 heart attacks per 1,000 patients.

Merck says the research does not show a problem with Vioxx. Instead, the company says, naproxen acted to reduce heart attacks by working much like aspirin.

The information from Merck's study was presented to the Food and Drug Administration in February when the companies asked for changes on their drug labels to reflect data showing that Vioxx and Celebrex caused fewer ulcers than other pain relievers.

In an April 27 report, Richard R. Stover, a pharmaceutical industry analyst at Arnhold & S. Bleichroeder Inc., did his own analysis of what he called "disturbing data" from Merck's study. In an interview, Mr. Stover said he was warning his clients, many of them institutional investors who hold Merck shares, that they should watch the issue carefully since it could hurt the company's stock price.

Some doctors, however, say they are worried about both drugs.

"There must be a warning," said Dr. M. Michael Wolfe, chief of the gastroenterology section at the

Boston University School of Medicine and a member of the F.D.A. advisory committee that reviewed the issue earlier this year.

"The marketing of these drugs is unbelievable," Dr. Wolfe added. "I'm sure there are many people out there who are taking these drugs that should not be."

Several doctors say they are worried about the possibility of heart attacks because many of the arthritis patients taking the drugs are elderly and have a higher risk of cardiovascular problems to begin with.

The current debate centers on whether the higher heart attack rate found in patients taking Vioxx is a result of the drug's actually causing damage in some patients or to an absence of the heart-protecting benefits that naproxen may have.

Merck's scientists say that naproxen appears to help reduce heart attacks by stopping or slowing the production of a substance called thromboxane. Thromboxane is thought to cause platelets in the blood to stick together, leading to blood clots.

"Naproxen had a similar antiplatelet effect to aspirin," said Dr. Eve E. Slater, senior vice president of external policy for Merck's research labs, "and those people had fewer heart attacks."

Neither Vioxx nor Celebrex have been shown to have the same heart-protecting benefit.

Dr. Slater also said that Mr. Stover's report was flawed and biased in favor of Pharmacia.

But regulators and some doctors say they still worry that there may be more of a problem with Vioxx.

And even if Vioxx and Celebrex do not damage the heart, the fact that they do not have the heart-protecting benefits of aspirin reduces the ability of the companies to market them as being significantly safer than other pain relievers.

In letters sent to physicians involved in Vioxx clinical trials, Merck recommended last year that doctors consider prescribing low doses of aspirin to patients taking Vioxx if they are at high risk of heart attacks. But those low doses of aspirin could increase the risk of ulcers — the main side effect that both Vioxx and Celebrex were developed to avoid.

The two drugs, known as Cox-2 inhibitors, have been shown to significantly reduce stomach ulcers compared with pain relievers like aspirin and ibuprofen. In rare cases, serious ulcers can lead to death.

So far, no studies have been done to measure whether patients have fewer ulcers if they take low doses of aspirin with either Vioxx or Celebrex.

At an F.D.A. advisory meeting in February, Dr. Maria Lourdes Villalba, a medical officer at the agency, summed up her analysis of Merck's study, saying that the company had proved that Vioxx, which is known generically as rofecoxib, caused fewer serious ulcers than naproxen. But she said that in her opinion, the potential safety advantage was offset by a higher risk of heart problems.

"Over all, there was no safety superiority of rofecoxib over naproxen," Dr. Villalba concluded, "mainly due to an excess of serious cardiovascular events."

Dr. Villalba said that because there were no studies that proved Merck's theory that naproxen worked like aspirin to decrease heart attacks, the F.D.A. was

concerned that the higher rate of heart attacks found with Vioxx might have been caused by the drug's producing blood clots.

Both Merck and Pharmacia say that patients taking either Vioxx or Celebrex and low doses of aspirin will still have fewer ulcers than if they were taking a drug combination like ibuprofen and aspirin.

Dr. G. Steven Geis, Pharmacia's vice president for arthritis and cardiovascular clinical research, said, "We believe that if a patient is on low-dose aspirin and needs a drug for arthritis, celecoxib is a good option."

Celecoxib is the generic name for Celebrex.

Dr. Slater of Merck said, "There is still a tremendous benefit with these drugs."

New York Times
June 12, 2001

NEWEST PAIN KILLERS DESERVE A CLOSER LOOK

BYLINE: JANE E. BRODY

What do stock analysts know about medical research? Last month Wall Street got nervous about the safety of two of the hottest prescription drugs on the market, Celebrex and Vioxx, after a company-sponsored study suggested that they might increase susceptibility to heart attacks.

The two are nonsteroidal anti-inflammatory drugs that greatly reduce the risk of ulcers associated with older over-the-counter and prescription rivals, ibuprofen (Advil and Motrin), naproxen (Aleve and Naprosyn), indomethacin (Indocin) and aspirin.

Celebrex, Pharmacia's top seller at $2.3 billion a year, and Vioxx, Merck's second-leading drug at $1.7 billion a year, are selective cox-2 inhibitors. Cox-2 is an enzyme, cyclooxygenase-2, that increases in arthritic joints, causing pain and inflammation.

The older products are nonselective inhibitors of cox-1 and cox-2. Cox-1 protects the lining of the stomach and intestines against damage by stomach acids; when it is inhibited, the lining is more likely to ulcerate. Within a week of starting the older drugs, more than 30 percent of patients develop gastric erosions or ulcers (often without symptoms), and within a year, about 3 percent have significant, sometimes fatal gastrointestinal bleeding.

So it is hardly surprising that, despite the high cost of Celebrex and Vioxx, in just a few years the

gastrointestinal safety factor has catapulted them into first place as the prescribed drugs to treat osteoarthritis.

Now that millions of people are taking them daily, questions of safety are arising. But it is important to distinguish between established risks and potentially false conclusions based on inadequate studies.

Are They Hazardous to Hearts?

It has long been known that regular use of aspirin reduces heart attack risks by inhibiting the formation of blood clots. And recent studies indicate that ibuprofen confers similar cardiac protection. Since the biological activity of naproxen is like that of aspirin and ibuprofen, it is reasonable to assume that it too will protect against heart attacks.

How would you interpret the findings of a study sponsored by Merck last year showing that patients taking Vioxx had risks of heart attacks four times as great as did patients taking naproxen? Would you conclude that Vioxx was risky or that naproxen had a protective effect not shared by Vioxx? Without a control group taking neither drug, telling whether Vioxx is hazardous or naproxen is beneficial is impossible.

Many doctors familiar with the biological activity of these drugs think the Merck study demonstrates what they have long suspected: that like aspirin and ibuprofen, naproxen protects against heart attacks. Better-designed studies are needed to tell who is right: Wall Street or these doctors.

All drugs can have side effects and potential hazards for some patients, and Celebrex (celecoxib) and Vioxx (rofecoxib) are no exceptions. The most common side effects of Celebrex (less so for Vioxx) are abdominal

pain, diarrhea and indigestion, which occur in just a few patients.

More serious concerns involve possible detrimental effects of cox-2 inhibitors on liver and kidney function. I take 25 milligrams of Vioxx daily (with no side effects), and my doctor insists that I have a blood test for liver function every three months. He is also unwilling to start prescribing Vioxx for patients over 60, some of whom may have hidden kidney disease that can result in high blood pressure and tissue swelling when this drug is taken chronically.

Caution is urged when cox-2 drugs are prescribed for those with known kidney disease, poor heart-lung function, liver disease or susceptibility to stress-induced ulcers.

They should not be used by people with severe kidney or liver disease. Other situations making their use inadvisable: cox-2 blockers should not be taken by those with sulfa drug allergies, asthma, hives or allergic reactions to aspirin or other nonsteroidal anti-inflammatory drugs and should be avoided by women in the third trimester of pregnancy and those breast-feeding.

Women trying to become pregnant may also want to avoid cox-2 inhibitors, since the cox-2 enzyme rises at ovulation and may be important for egg release, as well as implantation of an embryo and establishment of a uterine blood supply.

Cox-2 inhibitors can interfere with the healing of active gastrointestinal ulcers, which should be successfully treated before the drugs are taken. Vioxx can interact badly with certain other drugs, including lithium, methotrexate and warfarin. And because cox-2

inhibitors lack cardiac protection, patients with heart disease are often advised to take a daily aspirin as well.

Effects of cox-2 inhibitors on bone metabolism require further study. The enzyme is involved in the regulation of bone remodeling, and appears to be used both by cells that build bone and those that break it down. So it is still unknown whether cox-2 inhibitors support or suppress new bone formation.

Other Notable Benefits

Cox-2 inhibitors are likely to have significant health-promoting effects beyond reducing the pain and disability of joint disorders and certain injuries. Like other nonsteroidal anti-inflammatory drugs taken regularly, cox-2 inhibitors are believed to decrease the risk of colon cancer, apparently, according to animal studies, by promoting the regression of polyps and preventing their development.

Other tumors that may be inhibited by cox-2 blockers are cancers of the stomach, head and neck, breast and esophagus, all of which are associated with a rise in cox-2 activity. Studies are under way to test the role of cox-2 inhibitors in cancer prevention.

Also exciting is the suspected protective role of cox-2 inhibitors in the brain. The cox-2 enzyme is involved in the brain deterioration associated with seizures and Alzheimer's disease. Earlier studies have indicated that chronic use of the nonsteroidal drugs can slow the progression of senility by reducing inflammation in the brain.

The National Institute on Aging is supporting a clinical trial in patients with Alzheimer's disease to determine if rofecoxib (Vioxx), naproxen or both can slow

the loss of cognitive and other functions. A total of 320 patients at 40 medical centers are being followed for 14 months to determine the benefits of the drugs on memory, attention, reasoning, language and orientation.

As research unfolds, there are likely to be continuing reports about potential benefits and risks associated with these new drugs. So stay tuned.

URL: http://www.nytimes.com

Los Angeles Times
June 18, 2001

HEALTH MATTERS WHEN HYPE STANDS IN FOR SOLID SCIENCE

BYLINE: TRUDY LIEBERMAN

Over the last decade some 30,000 women with late-stage breast cancer received an expensive therapy known as autologous bone marrow transplantation. The treatment, costing $50,000 to $100,000, involved high doses of chemotherapy and the transplant of bone marrow cells in an attempt to arrest the disease. It offered hope but little evidence that it would prolong or improve the quality of life.

Doctors, hospitals, patients and their advocates, all with a stake in the procedure, fought for its use while insurers resisted on the grounds that it was experimental—that there was little proof that it worked. Battles between insurers and patients over the procedure made national headlines: A Southern California jury in 1993 awarded millions to the family of a breast cancer patient who died after her HMO refused to pay for ABMT treatment.

Two years ago, results from four clinical trials showed that insurance companies—some of which had bowed to public pressure and had begun paying for the procedure—had been right all along. The lack of evidence for ABMT is hardly an isolated example. If you look closely at many of the things done to patients, the evidence for their use often is soft or even nonexistent. For decades physicians placed tubes in the ears of kids with chronic ear infections in the belief that they would improve hearing and language development. A recent

review of the evidence, however, shows that tubes don't have much of an effect after all.

Several studies show that the proportion of medical interventions firmly grounded in evidence is much smaller than most people realize. "The public is shocked when they hear that 80% of medical practice is not based on evidence," says Dr. Gregg Meyer, who directs the Center for Quality Improvement and Patient Safety at the federal Agency for HealthCare Research and Quality. Much of what doctors do is based on opinion and consensus but that doesn't always produce the best outcomes and highest quality care. However, says Meyer, consensus "isn't always bad. There has never been a randomized controlled trial of penicillin for strep throat but we know it works."

But sometimes consensus is scary, especially when sellers of new treatments, tests, drugs and devices take to the airways to shape public opinion. Doctors are part of the public too. With help from the media, sellers sometimes promote treatments whether or not research has proved them effective. In 20 seconds Oprah can generate more demand for a medical procedure than one or two well-done clinical trials reported in the New England Journal of Medicine. Hype, promotion and public relations can overwhelm whatever science there is, and if there isn't any, they become a substitute.

The arthritis drug Celebrex and its cousin Vioxx, which is prescribed for arthritis as well as acute pain, show what can happen. Celebrex is now the sixth bestselling drug, generating more than $4 billion in sales since its debut in early 1999.

"The question prescribers have to ask is how did Celebrex reach $1 billion in sales at a time when there

wasn't a single controlled trial published that looked at the effectiveness in treating arthritis and pain compared to similar drugs," says Larry Sasich, a pharmacist who works with the Public Citizen Health Research Group. "What sources of information do prescribers use to choose drugs? In the case of Celebrex, because there was no science, the decision had to be based on promotional materials."

Meyer says his 6-year-old son, who watches fewer than three hours of television each week, can hum the Celebrex song. So can I, and I watch almost no TV and have no need for the drug. Doctors can, too, and that's when marketing that implies greater safety or efficacy than may be warranted becomes dangerous.

When Celebrex came on the market, Searle, which then made the drug, pointed to clinical trials that showed the drug caused fewer stomach ulcers than comparable medicines, known as nonsteroidal anti-inflammatory drugs, or NSAIDs. Indeed, its apparent gastrointestinal safety became its promotional raison d'etre.

However, the studies did not reflect strong enough evidence for the FDA to allow Searle to market the drug without a warning—also carried by other NSAIDs—that it could cause gastrointestinal bleeding and should be avoided by people with severe liver and kidney problems.

At the time, a study at the University of Pennsylvania, which was funded by Searle, discussed the possible risk of blood clotting that could result in heart attacks and strokes and recommended larger clinical trials. The study's senior author said the findings raised a red flag. But Searle dismissed the study as reaching "highly speculative conclusions." That study got little media attention.

The science is beginning to accumulate on Celebrex and Vioxx, which is manufactured by Merck. A study reported last July in the Annals of Internal Medicine found that both drugs reduced kidney function in older people who were otherwise healthy. And a scientifically valid study of Celebrex in the Journal of the American Medical Assn. last fall raised questions about its gastrointestinal advantages compared to similar drugs.

"There was no significant safety advantage in the GI tract," says Dr. M. Michael Wolfe, chief of gastroenterology at Boston Medical Center and a member of FDA's advisory panel on gastrointestinal drugs. However, Judith Glova, a spokeswoman for Pharmacia, which now makes Celebrex, said that "additional analysis showed clinically meaningful results."

A trial involving Vioxx found that it was easier on the stomach than naproxen, another NSAID sold under the brand names Naprosyn and Aleve. But this study raised a new red flag. Patients taking Vioxx had four times the risk of heart attacks as patients taking naproxen. "We're not sure whether Vioxx was associated with more heart attacks or naproxen was acting as aspirin to prevent heart attacks," Wolfe says.

Although warnings have surfaced, early hype for the drugs may be getting in the way of sound medical judgment. A doctor friend of mine tells of an 80-year-old patient who was in a rehabilitation facility after a minor fall. She had a history of arthritis, heart and kidney problems. The facility's cardiologist prescribed Celebrex, and soon the woman developed symptoms of heart and renal failure.

When my friend asked doctors at the facility if Celebrex could have caused her problem, at first they said no, replying that the drug did not have a "side effect profile." Later they conceded it could have been the culprit. "This fits the definition of an adverse drug event that went unrecognized," my friend says. Apparently doctors were confusing the advertised gastrointestinal advantages of the drug with other potential problems that received little publicity.

More than a decade ago, David Eddy, a physician and medical commentator, wrote in the journal Health Affairs: "Physicians can do more to admit the existence of uncertainty both to themselves and to their patients. While this will undoubtedly be unsettling, it is honest, and it opens the way for a more intensive search for ways to reduce uncertainty." Patients, he said, "can push the process by asking questions. There are few things better than asking questions to force research to get the answers."

With the explosion in technology and sophisticated marketing techniques, Eddy's comments are even more relevant today.

Trudy Lieberman is the author of "Consumer Reports Complete Guide to Health Services for Seniors" (Three Rivers Press, 2000). Send comments to: trudyal530@aol.com. Health Matters appears on the third Monday of the month.

GRAPHIC: Arthritis drug Celebrex is marketed with a catchy tune.

Associated Press
August 21, 2001

REPORT SUGGESTS HEART LINK WITH CELEBREX, VIOXX, BUT CRITICS SAY MORE RESEARCH NEEDED

BYLINE: BY LINDSEY TANNER, AP MEDICAL WRITER

The popular and heavily promoted new arthritis drugs Vioxx and Celebrex have been linked by researchers to a small but troubling increase in the risk of heart attacks and strokes. Critics say the analysis is flawed and no cause for alarm.

Still, many agree the issue needs to be studied because millions of people take the drugs, known as cox-2 inhibitors.

The researchers analyzed four studies that were not designed to examine the drugs' effects on the heart. Until such research is done, doctors should use caution in prescribing them to patients with heart disease, said Dr. Eric Topol, co-author of the analysis and chairman of cardiovascular medicine at the Cleveland Clinic.

Topol said he uses such medication himself for knee arthritis, "but if I had known heart disease, I would be concerned."

The analysis, published in Wednesday's Journal of the American Medical Association, included a study that looked at the gastrointestinal side effects in 8,076 patients taking Vioxx or the pain reliever naproxen. Vioxx patients faced double the risk of serious cardiovascular problems, including strokes and heart attacks, though only 111 Vioxx patients had them. Two

smaller Vioxx studies also suggested potential heart problems, Topol said.

Also, a study of 7,968 patients using Celebrex or two other pain relievers showed a slight but statistically insignificant increase in cardiovascular side effects with Celebrex, but the numbers were "trending in the wrong direction," Topol said.

An advisory panel warned the Food and Drug Administration in February of the Vioxx-naproxen study and said Vioxx should carry a warning label about potential cardiovascular risks. The FDA has not yet ruled on that recommendation.

Cox-2 drugs are touted for their ability to relieve pain without the gastrointestinal upsets of aspirin and other medications and are among the most popular medicines worldwide. They are expected to generate $6 billion in sales and 200 million prescriptions in the United States alone this year, Topol said. Celebrex and Vioxx are widely advertised on television and in magazines.

Skeptics said the researchers presented incomplete and misleading data.

"It's inappropriate at this point to rush to a conclusion that these drugs pose a serious cardiovascular risk," said Dr. Thomas Schnitzer, a Northwestern University rheumatologist. The analysis "is very far from proof."

Vioxx manufacturer Merck & Co. and Pharmacia Corp., which makes Celebrex, disputed the analysis and said their drugs are safe.

Dr. Laura Demopoulous, Merck's senior director of cardiovascular clinical research, noted that the Vioxx study involved patients with rheumatoid arthritis, a

disease that raises the risk of heart trouble. She also said the results may reflect naproxen's potential heart-friendly benefits rather than any negative effects from Vioxx.

Dr. Steve Geis, Pharmacia vice president for clinical research, said comparing studies involving different drugs and patients with different types of arthritis "is misleading and it is not quite accurate."

Dr. John Klippel, medical director for the Arthritis Foundation, said some of the studies included patients taking aspirin, which can benefit the heart by thinning the blood. Still, Klippel said the analysis raises important questions.

"We have to reassure people that these drugs are safe, yet there does seem to be some caution, particularly for people who are at increased risk of cardiovascular disease," he said.

Dr. Leslie Crofford, a University of Michigan rheumatologist, said the analysis will force doctors to consider such issues when prescribing arthritis medication.

While the new drugs might be better for patients at risk for gastrointestinal problems, "there's absolutely no data that these drugs are better for arthritis than traditional" pain relievers, she said. "They're good drugs, and for the right people, they can make a big difference. But they're not for everybody."

On the Net:

JAMA: http://jama.ama-assn.org

FDA: http://www.fda.gov

Bloomberg
August 21, 2001

MERCK, PHARMACIA PAIN DRUGS TIED TO HEART ATTACKS, STUDY FINDS

Merck & Co.'s Vioxx and Pharmacia Corp.'s Celebrex, pain drugs taken by millions and generating more than $5 billion in annual sales, may cause blood clots and heart attacks, according to research in tomorrow's Journal of the American Medical Association.

About one in 200 patients may suffer a heart attack while on the drugs, according to the research, which reviewed clinical studies of the two drugs and examined reports of heart problems compiled by the U.S. Food and Drug Administration.

The drugs are taken by so many people that heart problems could become a significant public health hazard, said Eric Topol, chairman of cardiovascular medicine at The Cleveland Clinic, which performed the research.

"These drugs could potentially lead to thousands of unexpected heart attacks a year in our country," said Topol, the senior author of a paper reporting the research. "It's incumbent on the manufacturers that they resolve this issue."

For most patients, the findings don't diminish the overall benefits of the drugs, which effectively control pain without causing stomach problems associated with older medications, experts said. The danger is for patients with heart problems, and studies are needed to measure their risk, said Topol, who said he takes the drugs himself for arthritis.

Both companies said The Cleveland Clinic's findings don't prove the drugs are unsafe.

Additional Data

"We already have additional data beyond what they cite, and the findings are very, very reassuring," said Laura Demopoulos, senior director of cardiovascular clinical research from Merck. "Vioxx does not result in any increase in cardiovascular events compared to placebo."

Officials at Pharmacia, which sells Celebrex with Pfizer Inc., pointed out the drugs' potential heart impact was extensively discussed at an FDA hearing in February. The review found Celebrex didn't increase a patient's heart risk, though some panel members expressed concern that patients on Vioxx were more likely to suffer a heart attack than those taking older pain medications.

Vioxx and Celebrex are different molecules and affect the body in different ways, said G. Steven Geis, group vice president of clinical research at Pharmacia.

"It's not unexpected that there would be differences in the side effect profile," he said. "We think the data shows there's no evidence whatsoever that there is an additional risk in taking Celebrex, while there may be an increased risk with Vioxx."

The authors of the study and other heart experts said more studies are needed to ensure the safety of the drugs and patients who take them. Taking Vioxx or Celebrex only periodically or with aspirin might reduce the potential risk of heart complications, although neither theory is proven and aspirin may nullify the drugs' gentler impact on the stomach, they said.

"It's too early to know if there is a clinically meaningful increase in cardiac events because of Vioxx and Celebrex," said Richard Stein, chief of cardiology at the Brooklyn Hospital Center and a spokesman for the American Heart Association. A clinical trial, funded by the companies or the government, is needed to resolve the uncertainties, said Stein.

The Cleveland Clinic researchers found the new painkillers raised blood pressure levels and were responsible for more than 100 heart attacks and other cardiovascular complications reported to the FDA. In addition, patients taking the drugs had more heart attacks than placebo-treated patients in separate studies, and patients on Vioxx in one large study had more heart problems than those taking an older pain medication, naproxen.

Comparisons between studies and among patients who are taking different drugs may be unreliable, the researchers said. Still, they offer insight into very rare side effects that otherwise wouldn't be apparent and may demonstrate the drugs' tendency to cause blood clots, they said.

"There is a good reason for doctors to be aware that there might be a small risk of cardiac events from putting a patient on" one of the drugs, said Stein, a professor at Weill-Cornell School of Medicine. "Doctors should think about not using it in high-risk cardiac patients."

Reuters
August 21, 2001

STUDY SEES HEART ATTACK RISK IN ARTHRITIS DRUGS

BYLINE: MICHAEL CONLON

Celebrex and Vioxx, popular anti-arthritis drugs projected to ring up U.S. sales in excess of $6 billion this year, may carry a risk of blood clots leading to heart attack and stroke, according to a study published on Tuesday.

The marketers of both prescription drugs disagreed with the findings, however, saying patient experience and other data showed they were safe.

The study from the Cleveland Clinic appeared in this week's Journal of the American Medical Association and was based on an analysis of previous clinical trials.

"The available data raises a cautionary flag about the risk of cardiovascular events with (these drugs).... Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents," it said.

Until then, it concluded, "We urge caution in prescribing these agents to patients at risk for cardiovascular morbidity."

The drugs were developed to fight often disabling arthritis inflammation without the stomach problems that can accompany aspirin and other anti-inflammatory drugs.

Called COX-2 inhibitors, they block an enzyme of that name that interferes with the production of chemical messengers that cause the pain and swelling of inflammation. But, the study said, the drugs may also promote the formation of clots in blood vessels by decreasing production of a compound that promotes the widening of those vessels.

"There should be careful assessment on a patient-by-patient basis," said Eric Topol, senior author of the report and chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic.

"The report reminds us once again that all drugs have both benefits and risks," added Steven Nissen, a co-author.

Pharmacia Corp. and Pfizer Inc. , which co-market Celebrex, the only U.S. drug approved for both osteoarthritis and adult rheumatoid arthritis, said the report was "inconsistent with the clinical experience of Celebrex."

They added that it was "essential to exercise extreme caution in drawing any conclusions" from an analysis of this type.

The companies quoted cardiologist David Brown of New York's Albert Einstein College of Medicine as saying "Celebrex studies have consistently shown no increased risk for heart attack and stroke, compared to traditional nonsteroidal anti-inflammatory drugs."

Merck , which markets the osteoarthritis agent Vioxx, said it "stands behind the overall and cardiovascular safety profile" of the drug. It said extensive safety data not included in the new report suggests "that there is no increase in the risk of

cardiovascular events as a result of treatment with Vioxx."

The report said use of the drugs has grown dramatically since their introduction in 1998, with more than $6 billion in sales and a prescription volume of 2 million expected this year in the United States. The drugs' literature already states that they and all nonsteroidal anti-inflammatory agents should be used with caution in patients with fluid retention, high blood pressure or heart failure.

Last month Britain's watchdog National Institute for Clinical Excellence said Celebrex, Vioxx and similar drugs should be limited to high-risk patients, not for safety reasons but on cost effectiveness grounds. It said high-risk patients would be those over 65 and people who suffer stomach problems from traditional anti-inflammatory drugs.

Dow Jones
August 21, 2001

VIOXX, CELEBREX USE RAISES CARDIOVASCULAR CONCERNS-STUDY

BYLINE: BETH M. MANTZ, DOW JONES NEWSWIRES

The safety of popular arthritis relievers is being questioned.

An analysis of clinical trials suggests a potential increase in the rate of heart attack, stroke and other cardiovascular events among patients treated with Vioxx from Merck & Co. Inc. (MRK) and Celebrex from Pharmacia Corp. (PHA) and Pfizer Inc. (PFE), according to an article in the Aug. 22-29 issue of The Journal of the American Medical Association.

The researchers didn't conduct new trials or report any new data on the COX-2 inhibitors. Instead, they analyzed four existing studies, including the Vioxx Gastrointestinal Outcomes Research, or VIGOR, and the Celecoxib Long-Term Arthritis Safety, or CLASS, to determine the effects of Vioxx and Celebrex on the risk of cardiovascular events. They compared the incidence of heart attack with the results of a meta-analysis of several large prevention trials.

The researchers acknowledge that their analysis has "several significant limitations." There have been no trials to date to pit Vioxx or Celebrex with aspirin against a traditional nonsteroidial anti-inflammatory drug with aspirin, such as ibuprofen or naproxen, for the purpose of evaluating the risk of cardiovascular events. Also, there haven't been trials designed to determine

whether the COX-2 class of drugs is protective or detrimental against heart disease.

However, the review of certain existing studies sent up warning flags to evaluate the blood-clotting tendencies of COX-2s, Eric Topol, senior author of the article and chairman of the Cleveland Clinic's department of cardiovascular medicine, told Dow Jones Newswires.

Because Vioxx and Celebrex are popular medicines with about $5 billion in combined sales last year, and millions of arthritis sufferers are at risk for developing cardiovascular problems, "these concerns must be addressed in dedicated trials," Topol said. "It could turn out that the COX-2s are very helpful but what we have so far indicates a higher heart attack rate."

Launched in 1999, Vioxx and Celebrex block the pain and inflammation enzyme while avoiding the enzyme that protects the stomach lining. They may help prevent hardening of the arteries but could lead to increased prothrombotic activity, which promotes the formation of blood clots.

According to the Cleveland Clinic research, which considered the various trial results of 48,450 patients, those patients given a placebo had a heart attack rate per year of 0.50%, while the rate with Vioxx was 0.74% and Celebrex was 0.80%.

"Even if the risk is a fraction of a percentage, that still means tens of thousands of people with possible heart attacks," said Topol, who is proposing a test comparing the COX-2s plus aspirin against a placebo plus aspirin.

The Cleveland Clinic's Topol and his colleagues think further studies could clear up questions about the risk:

whether it stems from the COX-2 class or the individual drugs; is related to the dose or frequency of the dose; or is affected by a low-dose of aspirin taken as a cardioprotective measure.

Merck, Pharmacia and Pfizer counter the researchers' suggestion. First, these drug makers do not believe their respective COX-2 inhibitors increases the risk of heart attack, stroke, unstable angina, and other cardiovascular events. The drug makers separately insist that their drugs are effective and safe, overall and with respect to the heart and cardiovascular system.

Pharmacia's and Pfizer's CLASS trial of 8,059 patients were randomized to receive Celebrex, ibuprofen or diclofenac; about 22% of these patients took low-dose aspirin for cardioprotection. The CLASS data did not show a significant increase in cardiovascular event rates compared with the NSAIDs, said Steve Geis, Pharmacia's group vice president of clinical research.

"We never saw any signal suggesting a cardiovascular problem," said Geis. "The theory put forward (by the article) about the effect of a specific COX-2 inhibitor on clot formation is just a theory, but there is no evidence to show that it is true."

Pharmacia also disputed the JAMA article's analysis on the grounds that the authors compared all of the CLASS patients, instead of the 78% of CLASS patients not taking aspirin for cardioprotection, to other patients not taking aspirin. Geis said a more appropriate analysis would have been to examine the 78% of CLASS non-aspirin users, in which the annualized rate of heart attacks was 0.33%.

Merck's trial of 8,076 rheumatoid arthritis patients compared the occurrence of gastrointestinal toxicity of

Vioxx with that of naproxen. Patients were not allowed to use aspirin. During the study, researchers observed fewer heart attacks in patients given naproxen compared to those given Vioxx, at a dose two times the highest chronic dose approved for osteoarthritis.

"We can't explain what is behind that observation and the authors point out the lower rate of cardiovascular events in those receiving naproxen may be the result of the beneficial effects of naproxen, which has aspirin-like profile in preventing platelet aggregation," said Laura Demopoulos, senior director of cardiovascular clinical research at Merck.

Understanding the relationship warrants further studies with placebo, said Demopoulos. But Merck has created an extensive body of cardiovascular data on Vioxx, which was excluded from the authors, and analysis, which suggests Vioxx doesn't increase the risk of cardiovascular events, she added.

Merck conducted its own meta-analysis of data from 19 clinical studies, involving more than 28,000 patients. This data was presented to the FDA advisory committee in February and presented at a medical meeting in June. Additionally, the company continues to evaluate data from ongoing studies with Vioxx and relevant emerging studies on COX-2 inhibitors to assess prospectively for cardiovascular risk and events.

Merck and Pharmacia criticized the Cleveland Clinic's analysis for the combining studies and inviting too many variables into the analysis. They combined lower-risk populations with higher-risk ones, differing backgrounds and treatment problems. In some of the trials, patients were barred from using aspirin as a cardioprotective measure.

"There may be complaints that we are comparing apples to oranges," said Cleveland Clinic's Topol. "Let's test apples to apples and put away this concern."

Until that data is collected, the article will have an effect on Vioxx and Celebrex use, said Hemant Shah, an analyst at HKS & Co.

"It changes the debate," said Shah. "This is the first time the supposedly breakthrough drug that has been promoted as a clean medicine is under attack. The only reason you would pay $2-$3 a day versus 20 cents is because of the safety over the NSAIDs. When you question the safety, there is no reason to pay that kind of money."

Even without conclusive support, the article brings harm to Merck, Pharmacia and Pfizer, which are hoping for sales of these COX-2s to accelerate and play major contributors to revenue. Instead of the moderate growth Shah was forecasting, the article and its potential publicity could bring a moderate decline in the growth of both Vioxx and Celebrex use.

New York Times
August 22, 2001

2 DRUGS LINKED TO INCREASED HEART RISK

BYLINE: THE ASSOCIATED PRESS

Researchers have linked chronic use of the popular and heavily promoted new anti-inflammatory drugs Vioxx and Celebrex to a small but troubling rise in the risk of heart attacks and strokes.

The researchers said, however, that their work was not proof that the link was real, and they called for studies to investigate it.

The drugs, cox-2 inhibitors, are used by millions of people.

The researchers analyzed four studies that were not intended to examine the drugs' effects on the heart. Until such research is done, doctors should use caution in prescribing them to patients with heart disease, said Dr. Eric Topol, co-author of the analysis and chairman of cardiovascular medicine at the Cleveland Clinic.

The analysis is to be published today in The Journal of the American Medical Association.

Cox-2 drugs have been promoted for their ability to relieve pain without the gastrointestinal upsets of aspirin and other medications. Merck & Company, which makes Vioxx, and the Pharmacia Corporation, which makes Celebrex, disputed the analysis.

Wall Street Journal
August 22, 2001

NOTE OF CAUTION: STUDY RAISES SPECTER OF CARDIOVASCULAR RISK FOR HOT ARTHRITIS PILLS — VIOXX AND CELEBREX MARKETERS DISPUTE THE RESEARCH, SOUGHT TO DOWNPLAY IT — A SPURNED APPEAL TO JAMA

BYLINE: THOMAS M. BURTON AND GARDINER HARRIS, STAFF REPORTERS OF THE WALL STREET JOURNAL

The blockbuster arthritis drugs Vioxx and Celebrex have had the most successful product launches in pharmaceutical history. The $3-a-day pills together generate $6 billion in annual sales, spurred by the hope that users may be spared the ulcers that older painkillers can cause.

But new research raises the possibility that the breakthrough drugs could have a worse side effect: an increased risk of heart attack.

The research poses the first serious threat to these drugs, which have been used by tens of millions of people world-wide since they came out in 1999. Its release follows an unusual behind-the-scenes push by marketers of the two drugs to lobby the prominent cardiologists who wrote the study and the journal that published it. The cardiologists, for their part, now fault the drug companies for failing to address adequately a potentially serious health concern.

Moreover, a study last year purporting to prove Celebrex's milder effects on the stomach than older remedies now appears exaggerated, because investigators for Pharmacia Corp., which is Celebrex's

manufacturer and co-marketer with Pfizer Inc., didn't publish half of the study's data. When the full set of data is crunched, Celebrex looks no better at avoiding ulcers than generic pills costing pennies a day. Merck & Co.'s Vioxx, on the other hand, does show a benefit in avoiding gastrointestinal side effects.

The cardiac concerns appear in an analysis by the noted cardiologists Eric J. Topol and Steven E. Nissen, chairman and vice chairman, respectively, of cardiovascular medicine at the Cleveland Clinic. Their study of Vioxx and Celebrex concludes, "Current data would suggest that use of these so-called `COX-2 inhibitors' might lead to increased cardiovascular events."

Their conclusions, published in today's Journal of the American Medical Association, are generally more critical of Merck's Vioxx. The authors say patients taking Vioxx had more than twice as many heart attacks, strokes and other cardiovascular events as patients getting an older, generic arthritis drug, naproxen. They conclude that Celebrex, too, seems to be associated with a relatively high rate of heart attacks.

The authors stress that their work is a new analysis of Merck's and Pharmacia's own raw data and of other past studies and not a new trial, so their conclusions aren't definitive. The marketers of the drugs and some outside experts dispute the conclusions.

The article also says part of the reason Vioxx didn't stack up as well might be that the drug it was compared with, naproxen, could have a heart benefit. It might prevent blood-clotting, in a fashion similar to aspirin.

The side-effect worries with Vioxx and Celebrex, as well as new problems being associated with popular

cholesterol-lowering drugs, result in part from their huge rise in usage. The problems are a reminder that even the safest and most beneficial drugs carry some risks, which are often magnified when a medicine is prescribed for millions of people.

Drs. Topol and Nissen, who collaborated on the research with cardiologist Debabrata Mukherjee, now of the University of Michigan, say they have tried unsuccessfully to persuade the makers of Vioxx and Celebrex to launch new clinical studies of the possible cardiac risks. "The reluctance to move forward is disturbing," Dr. Topol says. "Either they're moving at glacial speed, or they're waiting to see what the fallout will be from this and other reports. We're staring at a major public-health issue."

Merck and Pharmacia say they believe no such clinical study is necessary. First, they say, no heart-attack risk emerged from their research. Moreover, they say research already is under way on Vioxx that should answer any remaining cardiac questions.

"I don't think there are any sound conclusions that can be drawn from this study," says Marvin Konstam, chief of cardiology at New England Medical Center, who is a consultant to Merck. Dr. Konstam says he has done a more extensive analysis of all Merck data on Vioxx and concluded "there is no suggestion of a cardiovascular risk" from the drug.

At Celebrex maker Pharmacia, Steve Geis, group vice president for clinical research, adds: "We have never seen in any of our databases that Celebrex has a higher rate of cardiovascular events."

The companies question the cardiac study's methodology, and so do some independent experts.

"They have taken data from different prospective trials and rearranged them, and that's a very dubious statistical approach," says Garret FitzGerald, chairman of the University of Pennsylvania's Department of Pharmacology and a longtime expert on this class of drugs. He was co-author of a study of the two drugs published two weeks ago in the New England Journal of Medicine that looked at the same data analyzed in JAMA and came to less-alarming conclusions. "This kind of data manipulation can be very distorting," Dr. FitzGerald says.

Even so, the repercussions from the cardiac study could be significant. One reason is the sterling reputations of the authors and of the Cleveland Clinic, one of the nation's most respected cardiology centers. Another is that purported side-effect advantages were what fueled the growth of these drugs in the first place.

Doctors have long fervently hoped the COX-2 inhibitors might have advantages over older pain pills like the first "miracle" pain drug, aspirin.

Aspirin, found in the inner bark of willow trees, in 1899 established the modern pharmaceuticals industry. But it also turns out to promote ulcers. So do other pain pills such as ibuprofen, naproxen and diclofenac, collectively called non-steroidal anti-inflammatory drugs, or NSAIDs.

All reduce pain and inflammation by inhibiting an enzyme called cyclooxygenase. For years, researchers tried to figure out if they could block that enzyme in the periphery of the body, where most pain is created, without interfering with its protective effect in the gut.

In 1989, Philip Needleman of Washington University in St. Louis postulated there might be two forms of

cyclooxygenase: one primarily in the gut and one primarily in the periphery, called cyclooxygenase-2, or COX-2. He moved to Monsanto Co.'s Searle drug unit — now owned by Pharmacia — and spearheaded the search for a molecule that would block solely COX-2. The result was Celebrex, launched in early 1999.

Four months later, Merck brought out its own COX-2 inhibitor, Vioxx.

Both were approved because tests with a scope that was snaked into the stomach showed they produced lower rates of visible ulcer-like lesions. However, although many users believe the drugs produce less stomach pain than older arthritis drugs, no one has ever proved that these visible lesions are indicators of ulcers. So the Food and Drug Administration, in approving the drugs, made the marketers print the same label warning as NSAIDs: that 2% to 4% of those using the drugs for at least a year could get ulcers.

Even so, the drugs caught on because doctors and patients believed they were less likely to cause gastrointestinal problems. To try to prove this belief — and rid their drugs of the label warning — the companies undertook larger studies and presented them to an FDA advisory panel in February.

The step backfired. The FDA panel, in an unusual move, published the research on the Internet. This disclosed that Pharmacia had a half year of Celebrex data beyond what it published — and the full, 12-month trial showed worse results regarding ulcers than did the six months of data published in JAMA. This surprised JAMA editors, who learned that the manufacturer had decided against submitting the full set of data to the journal.

Defending that decision, Jay Goldstein, professor of medicine at the University of Illinois at Chicago and one of the Celebrex study's authors, says the extra data were statistically suspect because a high number of patients dropped out during the study's second six months. The authors worried that JAMA wouldn't publish the study with such suspect data, he says.

But JAMA's editor, Catherine D. DeAngelis, says the company and study authors should have told her about the extra data and allowed the journal to help decide just what to publish. "I was very upset when I found out that they had a full year's data," she says.

As FDA officials combed through all the data, say people familiar with the events, they also grew concerned about the apparently high rate of cardiac events, especially in Merck's data on Vioxx. The agency enlisted Dr. Nissen to assist with the FDA arthritis advisory committee's evaluation of the heart data. He soon grew concerned that Merck and its own clinical investigators hadn't, in his view, sufficiently emphasized the cardiac issue.

This wasn't a trifling worry. Millions of older people — those most prone to heart disease — take these arthritis drugs. So Drs. Nissen and Topol decided to air the issue. "We asked, 'What's going on here? Are these companies being forthright?' " Dr. Topol recalls. "I wouldn't say this was buried, but the appropriate cautionary flag wasn't raised."

Merck sought to downplay the cardiac issue — in meetings in New York and Cleveland with Cleveland Clinic doctors, in e-mails and in phone calls to the Cleveland doctors and the editor of JAMA. Pfizer also sought to minimize the issue in phone calls from one of

its senior scientists, Mitchell Gandelman, to the Cleveland Clinic, according to one person familiar with the events. Laura Demopoulos, who is Merck's senior director of cardiovascular clinical research, and Alise Reicin, a senior director of clinical research, met with Dr. Topol in Cleveland. Dr. Reicin and Peter DiBattiste, Merck director of cardiovascular clinical research, met with Dr. Nissen in New York.

"We were trying to provide background," says Dr. Demopoulos. This included data provided to the FDA and since published from 19 studies and 28,000 patients comparing Vioxx with placebos and NSAIDs. She says these data show no increase in cardiac events.

Pfizer's Dr. Gandelman declines to comment, but Pfizer in a statement says it "did not — and never would — attempt to discourage Drs. Nissen or Topol from publishing their analysis."

Merck's vice president of medical communications, Laurence Hirsch, asked Dr. DeAngelis at JAMA to carry a rebuttal from Merck in today's issue. She angrily refused.

"It was quite extraordinary and almost humorous that the company would do this," says Dr. Topol about Dr. Hirsch's call. Dr. Hirsch declines to comment, but a Merck spokesman says the company simply felt its data should be available to readers simultaneously with the Cleveland Clinic analysis.

The largest Vioxx study analyzed by the Cleveland Clinic authors included 8,076 rheumatoid-arthritis patients treated for up to 13 months with either Vioxx or naproxen, the cheaper pill. Forty-five Vioxx patients suffered a serious, clot-related cardiac event during the study, compared with 20 in the naproxen group. These

events included heart attack, unstable angina, cardiac clotting, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke and transient ischemic attacks, or ministrokes. Such events were 2.38 times as frequent in the Vioxx group as in the naproxen group.

By contrast, in Pharmacia's yearlong study of 8,059 patients, there was "no significant difference" in cardiac events between patients on Celebrex and those taking other low-cost NSAIDs, diclofenac and ibuprofen.

But then the Cleveland Clinic researchers took the unusual step of comparing the rate of cardiac events among Vioxx and Celebrex patients with that in 23,407 medium-risk cardiac patients given placebos, in various heart-attack prevention trials. Statistically, such a step can be iffy, because different study populations may have different heart-attack risks. Still, the doctors concluded the heart-attack rates with Celebrex and Vioxx were high enough to be of concern: The annualized heart-attack rate in placebo patients was 0.52%. With Vioxx, it was 0.74%, and with Celebrex, 0.80%.

"The risk is very low of inducing a heart attack," says Dr. Topol, "but this is tens of millions of people" taking these drugs.

Rheumatoid arthritis may itself increase the risk of heart attack. Most of the patients in the Vioxx study had this disorder, though not those in the Celebrex trial, who mostly had osteoarthritis. Pharmacia's Dr. Geis dismisses the cardiac study's findings, calling the practice of comparing different study populations "inaccurate."

Dr. Nissen acknowledges the study's limitations but says, "We were trying to get an overall impression of

what was going on. We think the evidence is there to warrant a lot of scrutiny."

As with any drugs, the risks of the COX-2 inhibitors have to be weighed against their benefits. The study of Vioxx showed that users had half the rate of ulcers and bowel perforations as those taking naproxen. Any drop in the risk of NSAID-related ulcers matters, because estimates are that nearly 100,000 Americans are hospitalized annually for these conditions and as many as 16,500 die of them.

Vioxx's study didn't show that it had eliminated the risk of ulcers, only that it had cut it in half, to 2%. Pharmacia failed to prove any reduction in ulcer risk in its trial — perhaps because many test patients were also taking aspirin. Celebrex also failed to prove that it reduced pain quickly, something Vioxx studies proved.

The FDA is unlikely to allow either manufacturer to cut or even soften its ulcer warning label, the companies agree. In light of the new data analysis, the agency could even require some warning about the drugs' effect on the heart.

All this is likely to spur managed-care firms' resistance to the drugs, a brewing rebellion that has led to slower sales growth than expected and a June 22 warning that Merck's earnings for the year would be lower than previously announced. Managed-care firms have been dubious that the drugs — which relieve pain and inflammation no better than far-cheaper pills — are worth their high prices.

Since 1999, Celebrex and Vioxx have claimed about half of the NSAID market. Sharon Levine, associate executive director of the Permanente Medical Group at Kaiser Permanente, contends that they should be given

only to chronic NSAID users who are old, taking steroids or have had ulcers. "Consumers are paying millions and millions for drugs that, for most of them, appear to have no clinical benefit" over much-cheaper pills, Dr. Levine says.

General Motors Corp., which last year spent $47 million providing the two drugs to its employees, believes at least half of those taking the drugs don't need them because they aren't at risk for an ulcer or don't need chronic pain care, says Robert Minton, a spokesman for GM's health-care initiatives.

One big reason for the drugs' popularity is marketing. In the 2001 first quarter, Celebrex and Vioxx were the second and third most heavily advertised drugs in the U.S., each with more ad dollars spent on it than Coca-Cola, according to ad-tracker CMR Inc. Three times the FDA has warned Pharmacia or Pfizer to stop exaggerating Celebrex's benefits to doctors and patients.

Washington Post
August 22, 2001

HEART RISK FROM CELEBREX, VIOXX?; 'SUPER ASPIRIN' MAKERS CONTEST ANALYSIS

BYLINE: DAVID BROWN, WASHINGTON POST STAFF WRITER

(CORRECTION: An Aug. 22 story incorrectly said that in a study of the painkiller Vioxx, patients were also allowed to take aspirin to help prevent heart attacks and strokes. It was a study of Celebrex, a painkiller similar to Vioxx, that permitted aspirin use. The Vioxx study did not permit aspirin use.)

The popular painkillers Celebrex and Vioxx may slightly increase a person's risk of having a heart attack, according to an analysis of clinical studies of the "super aspirin" drugs.

The analysis, which was strongly contested by the makers of the drugs, does not say the drugs unquestionably increase cardiovascular risk. It says only that it's possible.

"It's a cautionary flag that seems to say that something is going on that needs further exploration," said Eric J. Topol, a cardiologist at the Cleveland Clinic and one of the authors of the analysis, which appears in today's Journal of the American Medical Association.

Since their introduction in 1999, the drugs, which are known technically as COX-2 inhibitors, have been among the nation's best-selling prescription pharmaceuticals. One of them, celecoxib, sold as Celebrex, was the sixth-leading prescription drug in sales dollars last year and has been used by 14 million people. The other COX-2 inhibitor is rofecoxib, sold as Vioxx.

The drugs are popular because they provide the same pain-killing effects as aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, but with less chance of causing ulcers and intestinal bleeding. Aspirin inhibits two closely related enzymes, COX-1 and COX-2. The new drugs specifically inhibit only the second (which is involved in pain and inflammation) while not affecting the first (which, among other things, is involved in protecting the lining of the stomach).

COX-2 inhibitors illustrate the pharmaceutical industry's ability to tailor-make a drug with the same benefits as its predecessors, but with fewer hazards. However, the analysis suggests that even such highly specific compounds may have unexpected hazards.

Topol and two other Cleveland Clinic physicians looked at the rate of cardiovascular events — such as heart attack, chest pain, sudden death and stroke — in two big clinical trials of COX-2 inhibitors.

In one trial, about 8,000 people with rheumatoid arthritis were randomly assigned to get either Vioxx or naproxen, an NSAID. There were more than twice as many cardiovascular events in the Vioxx group as in the naproxen group — 46 vs. 20.

The researchers then looked at the small number of people who had a history of heart disease going into the study. These people were supposed to be excluded from the trial, because most people with heart disease take daily aspirin, and aspirin use was not permitted in the study. As is usually the case in large studies, however, a retrospective review uncovered a small number of people — 321 in this case — who should have been excluded but weren't. Among them, those taking Vioxx were four

times as likely to have a cardiovascular event as the ones taking naproxen.

There are two explanations for those observations. Vioxx may have increased the risk of cardiovascular events. Alternatively, naproxen may have lowered it.

The second study the Cleveland Clinic researchers looked at involved Celebrex. About 8,000 arthritis patients were randomly assigned to get either Celebrex or one of two NSAIDs, ibuprofen or diclofenac. There was no difference in cardiovascular events among the groups.

In the Vioxx trial, however, people were allowed to take low-dose aspirin for heart disease, and about 20 percent did. Topol and his colleagues theorized that aspirin use may have counterbalanced Vioxx's possible risk to heart patients.

Data from the studies were presented to an advisory committee of the Food and Drug Administration in February. Two FDA officials said yesterday that the agency is continuing to review the cardiovascular safety of COX-2 inhibitors to determine whether new information needs to be added to the drugs' labels, which is the information that accompanies each prescription.

The makers of the drugs strongly defended their safety yesterday.

"Both Pharmacia and Pfizer [which co-market Celebrex] strongly support the cardiovascular safety profile of Celebrex," said John Fort, a vice president for medical affairs at Pharmacia. He added that the company had specifically looked at patients with cardiac risk factors in the Celebrex trial and found no increase in events among those on the COX-2 inhibitor.

A physician at Merck, which makes Vioxx, said that company has examined the rate of cardiovascular events in several other studies in which some people got a COX-2 inhibitor and some got a placebo. One is a study — still ongoing — in which Vioxx is being tested as a possible way of slowing the course of Alzheimer's disease in people with mild dementia.

There has been no excess of events in people on Vioxx, said Laura Demopoulos, senior director for cardiovascular clinical research. She added that over the next few years, more such comparisons will be available.

Testing COX-2 inhibitors' potential hazards in heart patients directly will be difficult, however. Aspirin is known to help heart patients, but there is unlikely to be a benefit from COX-2 inhibitors alone. Testing it in heart patients to see only if it is a hazard would not be ethical.

It's possible that COX-2 inhibitors plus aspirin might be better than aspirin alone. That's because in some people with heart disease, there seems to be inflammation in the coronary arteries, which supply blood to the heart muscle. COX-2 inhibitors might help suppress the inflammation.

Topol, in fact, has proposed to the makers of Vioxx and Celebrex that they help finance a study to test that idea.

Financial Times
August 22, 2001

HEART ATTACK LINK TO ARTHRITIS DRUGS

BYLINE: ADRIAN MICHAELS

Merck, Pharmacia and Pfizer will on Wednesday be put on the defensive over independent scientific evidence that their billion-dollar arthritis drugs could be linked to an increase in heart attacks.

Merck's Vioxx and Pharmacia's Celebrex – which it co-markets with Pfizer – have become successful medicines for treating inflammation and are both expected to garner more than $3bn in sales this year.

The two drugs have been vying for market share, and have been trying to prove their worth over older pain-killers that are typically far cheaper.

The companies involved have been campaigning to have better warning labels on the drugs approved by the US Food and Drug Administration.

However, an analysis of clinical trials by scientists from the Cleveland Clinic Foundation suggests that there is a potential increase in the rate of heart attacks, strokes and other cardiovascular events among patients on the drugs.

The scientists, who report in the latest issue of the Journal of the American Medical Association, say that the data "raise a cautionary flag."

"Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents."

The study suggests that Celebrex only seems to do better on cardiovascular concerns because Pharmacia's own large research project allowed patients also to take aspirin, a well-known aid in combating heart problems, merck's research on Vioxx did not permit aspirin use.

The Cleveland scientists conducted an overview of several large trials, pooling the results of clinical data and independent studies. The combined analysis included almost 50,000 patients and showed comparable heart attack data for both Celebrex and Vioxx.

Pharmacia and Pfizer have responded by saying: "The article . . . is not based upon any new clinical study. The companies believe it is essential to exercise extreme caution in drawing any conclusions from this type of analysis."

The two companies point out that the cardiovascular effects of the drug were studies by the FDA in February.

"Celebrex studies have consistently shown no increased risk for heart attack and stroke, compared with traditional [older pain-killers] studied," said David Brown, a cardiologist, in the Pfizer and Pharmacia statement.

Reuters
August 22, 2001

UPDATE 1-ANTI-ARTHRITIS DRUGMAKERS TAKE HIT AFTER STUDY

BYLINE: BY EDWARD TOBIN

(Recasts, adds analysts comment, updates stock price, paragraphs 5, 8, 17, 18.)

Shares of Merck & Co Inc. and Pharmacia Corp. are expected to remain under pressure after a roller coaster trading day on Wednesday set off by a study questioning the safety of their popular anti-arthritis medicines, Vioxx and Celebrex.

The study by top cardiovascular researcher Eric Topol, who chairs the Department of Cardiovascular Medicine at the Cleveland Clinic, said the medicines may carry a risk of blood clots leading to heart attack and stroke.

The stocks spent most of the day on the downside before a late rally. Pharmacia, which makes Celebrex, closed at $43.20, down 96 cents, after being as low as $42.48. Merck, which makes Vioxx, closed at $71.22, up 47 cents, after being as low as $69.19.

Before the study was released late on Tuesday, Merck and Pharmacia, the world's third-and ???kers respectively, were already in negotiations with the U.S. Food and Drug Administration on a new label for these medicines.

The new label was expected to help them gain more market share from older pain medicines like aspirin and ibuprofen, and put an end to the debate over the

effectiveness of their drugs, members of a class of drugs called COX-2 inhibitors.

But Wall Street analysts said the study will fuel debate over the two drugs, threatening already slowing sales.

"Until we see some resolution of these issues, I think Merck and Pharmacia's stock will remain under pressure," said pharmaceuticals analyst Hemant Shah of HKS & Co.

Richard Evans of Sanford Bernstein said that "with a study like this coming from someone like Topol, the debate becomes more apparent to physicians and consumers.

"I think the average physician now will be more circumspect about writing prescription for these drugs, and your average consumer will be less likely to ask for the drug from their doctor," Evans said.

Pfizer , which co-markets Celebrex with Pharmacia, ended the day 4 cents higher at $40.68.

Both Vioxx and Celebrex have seen slowing sales growth recently, as some insurers have refused to reimburse patients for them, opting instead for much cheaper conventional pain and arthritis treatments.

Shah called Topol's study a "very important event in the life of Cox-2" drugs, which block the enzyme of that name that interferes with the production of chemical messengers that cause the pain and swelling of inflammation.

"I had expected very moderate growth at best over the next 12 months for Cox-2 drugs," he said. "I now conclude that there will be no growth, and these drugs will start to lose market share to older generics like

ibuprofen and sales will begin to decline. That will be the best case scenario," he said.

STUDY CITES HEART ATTACK RISKS

Researchers from the Cleveland Clinic said in the study that available data regarding the arthritis drugs, which are expected to reach $6 billion in sales this year "raises a cautionary flag about the risk of cardiovascular events with (these drugs)." They called for a trial specifically assessing cardiovascular risk and benefit the COX-2 inhibitors.

The study said the drugs may also promote the formation of clots in blood vessels by decreasing production of a compound that promotes the widening of those vessels.

The drugs were developed to fight often disabling arthritis inflammation without the stomach problems that can accompany aspirin and other anti-inflammatory drugs.

Merck, based in Whitehouse Station, New Jersey, and Pharmacia, based in Peapack, New Jersey, disagreed with the findings, saying patient experience and other data showed they were safe.

The FDA reviewed data from the two clinical trials used for Topol's study in February, and did not conclude there was a cardiovascular issue with Celebrex, but did vote to include cardiovascular warnings in the Vioxx label.

"Old or new, flawed or unflawed this article is not going to be helpful to this class of drugs," said analyst Stephen Tighe of Merrill Lynch.

Pharmacia is seen as having the biggest risk to a COX-2 sales slowdown because Celebrex their biggest driver.

Celebrex accounted for $710 million of Pharmacia's $5.4 billion in quarterly revenues in the second quarter. Merck's Vioxx accounted for $725 million of its $11.9 billion quarterly revenue.

"Vioxx is a big driver for Merck, but they have other drugs there that are still growing well, so it may have less of an impact. Pfizer, which co-promotes Celebrex, can weather storm pretty well," said Ravera.

As long as the clouds remain on the horizon for the COX-2 drugs, analysts see continued weight on the stocks.

"Until we see some resolution of these issues, I think Merck and Pharmacia's stock will remain under pressure," said HKS's Shah.

Los Angeles Times
August 22, 2001

THE NATION STUDY FINDS HEALTH RISKS IN POPULAR ARTHRITIS MEDICINES VIOXX, CELEBREX

Researchers say the added 1% chance of heart attacks and strokes may be mitigated by aspirin and is not enough to ban the drugs.

BYLINE: THOMAS H. MAUGH II, TIMES MEDICAL WRITER

Two of the most widely used new drugs for arthritis may increase a patient's risk of heart attack and stroke and probably should not be used by people who already are at high risk for cardiovascular problems, researchers from the Cleveland Clinic report today.

More than 2 million prescriptions for the drugs Vioxx and Celebrex are expected to be written this year. The drugs' ability to relieve pain is similar to that of aspirin and other over-the-counter medicines. But unlike aspirin, they do not damage the stomach and gastrointestinal system—a major advantage for people with chronic pain that has helped lead to an expected $6 billion in sales of the two drugs this year.

But the study reported in today's issue of the Journal of the American Medical Assn. offers a cautionary note on their use. The report reviewed previous studies of the two drugs and suggests that they can increase formation of blood clots, leading to heart attacks and other cardiovascular problems.

Dr. Eric J. Topol and his colleagues note, though, that the added risk is still very small—less than 1%. Moreover, patients who take Celebrex or Vioxx routinely

might be able to reduce or eliminate the risk by adding daily low doses of aspirin to their drug regimens, they said.

Topol himself takes the drugs because of an arthritic knee. They are "a great class of medicines," he said. "But if I had risk factors for heart disease, I would be more concerned right now. I would take aspirin or switch drugs until we have more concrete evidence."

The report, added co-author Dr. Steven Nissen, "reminds us once again that all drugs have both benefits and risks."

The manufacturers of the two drugs disputed the study, arguing that it is poorly designed and that it doesn't include unpublished results obtained from thousands of other patients.

When the drugs are compared directly to placebos, "we find absolutely no difference in risk" for cardiovascular disease, said Dr. Laura Demopoulos of Merck & Co., which manufactures Vioxx.

Representatives of the U.S. Food and Drug Administration took issue with Merck's assertion, however. Much of the data still need to be evaluated, they said.

"We would not agree that there is no cardiovascular risk," said Dr. Lawrence Goldkind, acting deputy director of the FDA's division of anti-inflammatory, analgesic and ophthalmic drugs. Nor would the agency say there is a risk. "We will continue to evaluate the information as more becomes available," he added.

Dr. Jack Klippel, medical director of the Arthritis Foundation, said, on balance, consumers who use the drugs should continue to do so. "We want to reassure the

vast majority of people who take these drugs that they are safe and continue to represent an important advance" in arthritis treatment, he said.

But, he added, patients with known risk factors for heart disease, such as obesity, high cholesterol levels and high blood pressure, "should discuss with their doctors whether a low dose of aspirin is needed."

Vioxx and Celebrex are members of a family of drugs called Cox-2 inhibitors, which are painkillers and anti-inflammatory drugs. Their ability to relieve pain without causing stomach distress is significant in light of the fact that each year for the last decade about 100,000 Americans were hospitalized because of ulcers and other gastrointestinal problems resulting from daily use of large doses of aspirin or other painkillers.

In their review, Topol and his colleagues analyzed all of the published studies of Vioxx and Celebrex, which included about 18,000 patients. But they focused primarily on two large studies, one for each of the drugs.

The first was a study of 8,076 patients who took either Vioxx or naproxen, a drug similar to aspirin, for arthritis pain. That study concluded that patients taking Vioxx had about 2.2 times the risk of a heart attack or stroke as those taking naproxen. The absolute number of serious cardiovascular events was very small, however: only 111 in the Vioxx group.

That study left unclear whether Vioxx caused an increase in heart attacks or whether the naproxen prevented them, Topol said. Small daily doses of aspirin are known to reduce the risk of heart attacks by inhibiting the formation of blood clots. Researchers believe that naproxen acts in a similar fashion.

The second study enrolled 7,968 patients who used Celebrex or one of two other pain relievers. That study showed a slight but statistically significant increase in heart attacks among the Celebrex patients, Topol said.

Results from smaller studies were similar.

The problem with all the published studies was that the Cox-2 inhibitors were compared to naproxen, aspirin or other drugs that could reduce the rate of heart attacks.

To determine whether they were observing a higher risk caused by Vioxx and Celebrex or simply a lowered risk caused by aspirin and naproxen, the Cleveland Clinic group compared the Vioxx and Celebrex users to a group of patients receiving a placebo in a large study that compared aspirin to a placebo. Using that control group, they concluded that the Cox-2 inhibitors doubled the risk of heart attacks.

"But that's like comparing apples to oranges," said Dr. John G. Fort of Pharmacia Corp., which distributes Celebrex. Arthritis patients have an increased risk of heart disease, while the control group in the aspirin study included mostly healthy patients with little risk, he said.

Dr. Carl Pepine of the University of South Florida agreed with Fort's assessment. "If there is a threat [from these drugs], it is extraordinarily low. And in the patients who are using aspirin, I don't think it is very convincing at all. I would hope that these very useful drugs are not abandoned based upon this article."

Plain Dealer (Cleveland, Ohio)
August 22, 2001

TWO ARTHRITIS DRUGS COULD HEIGHTEN RISK FOR HEART PATIENTS

BYLINE: ROGER MEZGER, PLAIN DEALER REPORTER

The two top-selling prescription drugs for arthritis could increase the risk of heart attack in some patients, according to an analysis by Cleveland Clinic cardiologists.

In a study being published today in the Journal of the American Medical Association, the Clinic doctors urge physicians to be careful in prescribing Celebrex and Vioxx to patients with coronary artery disease.

"What we're really calling for is more trials that need to be done by the manufacturers of these drugs . . . to get the answers that are vital in the interest of public health," said Dr. Eric Topol, principal author of the study and head of cardiovascular medicine at the Clinic.

But Pharmacia Corp., maker of Celebrex, and Merck & Co., which makes Vioxx, said they had not seen an increase in heart attacks and questioned the validity of the Clinic study.

Last year Celebrex was the ninth-most-prescribed drug in the world, according to IMS Health, which tracks the pharmaceutical industry. At more than $2 a pill, Celebrex and Vioxx had combined sales of $4.5 billion last year and topped $2.6 billion in the first half of this year.

The Clinic researchers drew their conclusions after taking a fresh look at four earlier studies that were

designed to see how painkillers affected the gastrointestinal system, not the heart.

From that data, they concluded that people who took Vioxx or Celebrex in two of the studies stood a 50 to 60 percent greater chance of having a heart attack or stroke than people in two other studies who took only sugar pills.

"There is a lot of hazard at being wrong," when data from previous studies is used to draw new conclusions, said Dr. Steven Nissen, who worked with Topol and Dr. Debabrata Mukherjee on the project. That is why the research team feels it is urgent that the companies now focus on the heart safety question in a new study, he said. Mukherjee, a cardiologist, is now at the University of Michigan.

Heart safety is an important issue for the drugs' main users: the elderly and people with rheumatoid arthritis. Both groups are at increased risk of cardiovascular disease.

Although Vioxx and Celebrex are safe and effective for most people, the questions being raised about their possible effect on heart patients demand more study, said Dr. John Klippel, medical director of the Arthritis Foundation.

Topol said the Clinic has offered to work with Merck & Co., which makes Vioxx, and Pharmacia Corp., maker of Celebrex, in designing new studies.

"Whether they do it with us or whether they do it with some other academic entities, they've just got to do it, that's the main thing," Topol said. "Because they're leaving in the lurch millions of people."

But Dr. Laura Demopoulos, head of cardiovascular research for Merck, and Pharmacia spokeswoman Mary-Fran Faraji were both noncommittal about the possibility of conducting further studies. Demopoulos said the Clinic doctors overlooked data from 19 other studies showing that Vioxx did not increase the risk of heart attack.

Food and Drug Administration spokesman Jason Brodsky said that because the heart safety issue is still under review at the agency, it would be premature for the FDA to say whether doctors should take precautions in prescribing the drugs.

Topol, however, said doctors should make sure that heart patients taking Vioxx or Celebrex also take low-dose aspirin to help offset the drugs' tendency to clot blood. Whether that combination is effective needs to be examined as part of a new study, he said.

Celebrex hit the market about 2 years ago, followed soon after by Vioxx. The so-called cox-2 inhibitors were immediate hits because they are easier on the stomach than aspirin and other painkillers like Motrin, Aleve and Naprosyn.

St. Petersburg Times (Florida)
August 22, 2001

"SUPER ASPIRIN" ALARM SOUNDED

WASHINGTON; CHICAGO. The popular painkillers Celebrex and Vioxx may slightly increase a person's risk of having a heart attack, according to a new analysis of clinical studies of the "super aspirin" drugs.

The analysis, which was strongly contested by the makers of the drugs, does not say the drugs unquestionably increase cardiovascular risk. It says only that's a possibility.

"It's a cautionary flag that seems to say that something is going on that needs further exploration," said Eric Topol, a cardiologist at the Cleveland Clinic and one of the authors of the analysis, which appears in today's Journal of the American Medical Association.

The researchers analyzed four studies that were not designed to examine the drugs' effects on the heart. Until such research is done, doctors should use caution in prescribing them to patients with heart disease, Topol said.

Since their introduction in 1999, the drugs, COX-2 inhibitors, have been among the nation's best-selling prescription pharmaceuticals. One of them, celecoxib, sold as Celebrex, was the sixth leading prescription drug in sales dollars last year and has been used by 14-million people. The other COX-2 inhibitor is rofecoxib, sold as Vioxx.

Vioxx manufacturer Merck & Co. and Pharmacia Corp., which makes Celebrex, disputed the analysis and said their drugs are safe.

Dr. Laura Demopoulous, Merck's senior director of cardiovascular clinical research, noted that the Vioxx study involved patients with rheumatoid arthritis, a disease that raises the risk of heart trouble. She also said the results may reflect naproxen's potential heart-friendly benefits rather than any negative effects from Vioxx.

Washington Post
September 4, 2001

YOU AND A: ARTHRITIS DRUGS; PAIN AND CONFUSION

BYLINE: FRANCESCA LUNZER KRITZ, SPECIAL TO THE WASHINGTON POST

An article in the Aug. 22/29 issue of the Journal of the American Medical Association (JAMA) suggested that popular arthritis drugs Vioxx and Celebrex may increase the risk of cardiovascular events — including heart attacks, strokes and chest pain. The news could affect millions of arthritis patients who currently use the drugs.

Approved in 1999, Vioxx and Celebrex generally help relieve pain without the gastrointestinal symptoms — such as stomach pain, bleeding and stomach ulcers — sometimes associated with many other non-steroidal anti-inflammatory drugs (NSAIDs) like aspirin and ibuprofen (such as Motrin and Advil).

Vioxx and Celebrex, which belong to a class of drugs called COX-2 inhibitors, hold more than 60 percent of the arthritis drug market and last year had combined sales of just over $ 4 billion. Vioxx was the nation's most heavily advertised prescription drug last year, according to IMS Health, a health information company; Celebrex ranked seventh in advertising.

Both Merck, which makes Vioxx, and Pharmacia, which makes Celebrex, dispute the findings reported in JAMA and insist their drugs are safe.

My doctor recently prescribed Vioxx for my arthritis. TV commercials make it look like a wonder drug. Should I ask for something else?

As you were about to guess, the answer is, "it depends" — partly on your risk for heart problems otherwise, and partly on other factors. The researchers who wrote the JAMA article, heart specialists at the Cleveland Clinic, examined four previously published studies on the drugs to see how many study subjects suffered cardiovascular events, including a blood clot, heart attack or stroke. So this was not research conducted specifically for the purpose of exploring negative effects on the heart, but an examination of data collected for other purposes to see if they provided any information about these drugs and heart problems.

Oh, so I can ignore the studies?

Well, no. To some experts, they suggest reason for concern. One study showed twice as high a rate of cardiovascular events for people taking Vioxx as for those who took naproxen, another pain reliever. However, the absolute incidence was low: 1.3 percent for the Vioxx group versus 0.67 for those taking naproxen. What isn't clear is whether Vioxx increased risk by causing blood platelets to clump together and thereby promoting a clot, or whether naproxen protected some people from heart attacks by keeping platelets from clumping together.

That doesn't sound good. What about the other studies?

A second study compared Celebrex to two other drugs commonly prescribed for arthritis: ibuprofen and diclofenac (Cataflam and Voltaren). Researchers found more heart attacks in the Celebrex group than other

groups, according to Eric Topol, the study's lead author and chairman of the Department of Cardiovascular Medicine at the Cleveland Clinic, although he said the difference was not statistically significant. However, some patients in this study also took aspirin, which can protect the heart from clots and heart attacks. The other two studies compared Vioxx with other arthritis drugs, and also included some aspirin-takers. Taken together, says Topol, the four trials consistently showed a small excess of cardiac events among the patients taking Vioxx or Celebrex.

Did all this concern about Celebrex and Vioxx and heart problems come out of the blue?

No. Rheumatologist Stephen Ray Mitchell, academic dean of the Georgetown University Medical School, said other published studies have raised concerns about the effect of Vioxx and Celebrex on platelets. And some members of an FDA advisory committee who reviewed Vioxx earlier this year thought the drug's label should include information on the study that compared Vioxx and naproxen and found more cardiovascular events among the Vioxx takers. The FDA has not yet made a final ruling on the proposed label changes.

So is one drug safer than the other?

Vioxx was linked to more heart attacks in these studies, but Celebrex seems to increase the risk as well, according to the researchers. John Klippel, medical director of the Arthritis Foundation, says the study raises concerns about both drugs and that one drug doesn't appear safer than the other when it comes to heart attack risk.

Do the the manufacturers plan any action in response to the new findings?

Pharmacia and Merck may consider the possibility of conducting clinical trials that would look specifically at cardiovascular risk, spokesmen for the companies said. The Arthritis Foundation and the American College of Rheumatology have called on both companies to do just that.

Mary-Fran Faraji, a spokeswoman for Pharmacia, said Pharmacia continually reviews data on the drugs. She said the JAMA article offers no new data and compares two completely different sets of patients — those taking aspirin against those who were not. She said no evidence of increased cardiovascular risk from Celebrex had been seen in 30,000 patients in Pharmacia-sponsored clinical trials.

Merck spokeswoman Chris Fanelle said similarly that her company's studies of 28,000 patients suggested "there is no increase in the risk of cardiovascular events as a result of treatment with Vioxx."

What should I do in the meantime?

If you take either drug, Klippel of the Arthritis Foundation advises, you may want to talk with your physician about considering a switch. People who should have the conversation soonest, he says, include those in higher cardiac risk groups such as the elderly, diabetics, smokers, people with a history of heart disease or people with high blood pressure.

Why shouldn't I just switch?

Because most alternatives, such as naproxen or ibuprofen, carry a risk of serious stomach disorders such as bleeding and ulcers; patients with a previous history of an ulcer or stomach disorder may be advised to stick with Vioxx or Celebrex, which were developed to solve that problem. Before you meet with your doctor, have a

look at the Arthritis Foundation's Drug Guide (www.arthritis.org/conditions/DrugGuide/drug_index.asp) so you can discuss options available to you.

What are the other drugs I'd most likely switch to?

If Celebrex or Vioxx gave you relief, chances are good your doctor will simply try another NSAID, such as aspirin, ibuprofen or nabumetone (Relafen). Klippel noted that while NSAIDs are chemically similar, people respond differently to them, so that if one doesn't work for you, another might. Some doctors prescribe misoprostol (Cytotec), a synthetic prostaglandin, along with NSAIDs to replace stomach-protecting enzymes that NSAIDs wipe out. A fairly new drug, Arthotec, combines diclofenac, an NSAID, and misoprostol in a single pill. A simple pain reliever such as acetaminophen (Tylenol), which doesn't have the gastrointestinal side effects of NSAIDs, may work fine for some patients but for others may not provide sufficient relief.

What if I keep taking Vioxx or Celebrex but add a baby aspirin to the regimen? Would that let me keep taking the drugs but also help protect against a heart attack?

Maybe, says Mitchell, though no studies have been done to prove this would be effective. And even low-dose aspirin raises the risk of stomach disorders. So talk with your doctor.

Is there any way to monitor for a blood clot, so I could keep taking the drug and just get off it if the doctor spots a problem?

Nope. Tests cannot predict clots.

Any other side effects of these drugs I should know about?

Like some other NSAIDs, Celebrex and Vioxx can, in rare cases, cause fluid retention and kidney problems or raise blood pressure. Your doctor should perform periodic blood tests to make sure markers that could indicate a problem aren't elevated.

Are Celebrex and Vioxx really more effective in relieving arthritis pain?

Celebrex and Vioxx's claim to fame is their lowered risk of stomach problems; they're actually no more effective in reducing pain than a host of other NSAIDs.

Bloomberg
September 24, 2001

MERCK MISREPRESENTS SAFETY OF VIOXX, FDA SAYS IN WARNING LETTER

BYLINE: KRISTIN REED

Merck & Co. misled doctors with marketing campaigns that underplayed potential heart risks associated with the company's blockbuster painkiller, Vioxx, government regulators said in a letter to the company.

The U.S. Food and Drug Administration cited Merck for minimizing "potentially serious" findings in a study that showed heart attacks were significantly more common among patients who took Merck's drug than in patients who were treated with a older generic painkiller called naproxen. The so-called Vigor study was released last April.

Merck is struggling to meet a $3 billion sales target for Vioxx this year in the face of competition from Pharmacia Corp.'s rival drug Celebrex. Merck has said heart attacks are more common among Vioxx patients, compared with those on naproxen, because the older painkiller also protects patients' hearts. In a warning letter to Merck, the FDA criticized that position, and told Merck to better publicize the potential heart risks of Vioxx.

"Minimizing these potential risks and misrepresenting the safety profile for Vioxx raises significant public health and safety concerns," the FDA said in a Sept. 17 warning letter. "Your misrepresentation of the safety profile for Vioxx is

particularly troublesome because we have previously. . . objected to promotional materials for Vioxx that also misrepresented Vioxx's safety."

The agency is asking Merck to stop using those marketing materials, to send a letter to doctors correcting any false impressions about Vioxx's safety, and to respond in writing to the FDA by Oct. 1 to explain how these steps will be accomplished.

Merck officials said they are preparing their response.

"We continue to stand behind the overall safety and the cardiovascular safety of the product, but our immediate priority is to discuss our response" with the FDA, said Christine Fanelle, a Merck spokeswoman.

In the nine-page letter, the FDA specifically objected to a series of audio conferences for health care workers that were led by an arthritis specialist and paid for by Merck. The FDA also reprimanded the company for claims sales representatives made about the drug's safety, and for statements in a May 22 press release that stressed Merck's belief in Vioxx's safety.

"Your claim in the press release that Vioxx has a 'favorable safety profile' is simply incomprehensible," the FDA wrote in the letter. "The implication that Vioxx's cardiovascular profile is superior to other (painkiller drugs) is misleading; in fact, serious cardiovascular events were twice as frequent" among Vioxx patients.

Reuters
September 24, 2001

MERCK VIOXX PROMOTIONS SAID MISLEADING ON SAFETY

BYLINE: LISA RICHWINE

U.S. regulators have charged drug giant Merck and Co. Inc. with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks.

The Food and Drug Administration, in a warning letter sent Sept. 17 and released publicly late Friday, ordered the company to stop using some promotional materials and to send a letter to healthcare providers to correct any false impressions.

The regulatory agency took issue with statements made during company-sponsored audio conferences, in a May 22 press release and by sales representatives at two medical meetings.

The FDA said the promotions minimized results of a trial that showed a higher rate of heart attacks among people treated with Vioxx compared with another pain reliever, naproxen.

Additionally, the FDA said Merck's materials downplayed a potentially dangerous interaction between Vioxx and anti-clotting drug Coumadin, known generically as warfarin.

"Your minimizing these potential risks and misrepresenting the safety profile for Vioxx raise significant public health and safety concerns," wrote Thomas Abrams, head of the FDA division of drug marketing, advertising and communications.

The mischaracterizations of Vioxx's safety were "particularly troublesome" because the FDA had warned the company about it in a previous letter, Abrams said.

Merck also made unsubstantiated claims that Vioxx was safer than other non-steroidal anti-inflammatory drugs, the FDA said. In addition, the company promoted Vioxx for unapproved uses such as relieving rheumatoid arthritis, preventing cancer and treating Alzheimer's disease and gout, the FDA letter said.

Vioxx is battling with Pharmacia Corp.'s Celebrex in a multi-billion dollar market to ease pain from arthritis. The drugs are known as COX-2 inhibitors.

A review of studies on the drugs, published in August, said both may carry a risk of blood clots that lead to heart attacks. Both makers disputed the findings.

According to the FDA letter, a doctor hired by Merck argued during an audio conference that naproxen, the generic painkiller that Vioxx was compared to in a large trial, protected the heart, which explained why naproxen patients had fewer heart attacks than Vioxx patients. The FDA said that reasoning was "hypothetical."

Merck spokeswoman Christine Fanelle said the company was developing a response to the FDA that it planned to submit by Oct. 1. "We continue to stand behind the overall safety and cardiovascular safety of Vioxx," Fanelle said.

The FDA sends hundreds of warning letters a year. Most issues raised in the letters are resolved without further regulatory action.

USA TODAY
September 25, 2001

FDA SENDS A WARNING LETTER TO MAKER OF VIOXX PAINKILLER

BYLINE: RITA RUBIN

The Food and Drug Administration has ordered Merck, maker of the blockbuster painkiller Vioxx, to issue a letter to doctors "to correct false or misleading impressions and information" stemming from the drug's promotional campaign.

Merck's marketing efforts, aimed mainly at doctors, have minimized Vioxx's known and potential cardiovascular risks, the FDA wrote in an eight-page "warning letter" faxed Sept. 17 to Raymond Gil-martin, president and chief executive officer. The letter, signed by Thomas Abrams, head of the FDA's Division of Drug Marketing, Advertising and Communications, was posted Friday on the FDA Web site.

Merck spokeswoman Chris Fanelle says her company will not comment on the letter until after it files a response to the FDA, which has set a deadline for Oct. 1. "We continue to stand behind the overall and cardiovascular safety of the product," Fanelle says.

So far this year, the FDA has sent drug companies fewer than a dozen warning letters, which the agency reserves for activities that raise significant public health concerns. Pharmacia, maker of Celebrex, Vioxx's main competitor, received one in February for violations similar to Merck's.

The two drugs are heavily promoted to patients and doctors, and sales are expected to hit $6 billion this year.

They are thought to be gentler on the digestive tract than other non-steroidal anti-inflammatory drugs, or NSAIDs, a group that includes aspirin and ibuprofen. However, the FDA has not yet given their makers permission to make that claim.

In the warning letters, the agency cautions both companies that the cited violations "do not necessarily constitute an exhaustive list." The letters state that the FDA is continuing to evaluate other aspects of the companies' promotional campaigns.

According to the Sept. 17 warning letter, a doctor under contract with Merck to present talks to other physicians, company sales representatives and a press release have minimized the possibility that Vioxx could increase users' risk of heart attacks or strokes.

In a study of 4,000 patients, those on Vioxx were more than twice as likely to suffer a serious cardiovascular complication than those on naproxen, another NSAID.

The Vioxx patients were five times more likely to suffer a heart attack.

Merck's promotional campaign has attributed that finding to naproxen's protective effect, which is possible but unproven, the warning letter states. Meanwhile, it says, the company's marketing efforts have ignored the possibility that Vioxx increases the risk of artery-clogging blood clots.

In February, an advisory panel recommended that the FDA require Merck to warn patients and doctors about an increased heart attack risk, but the agency has not yet asked the company to add that information to Vioxx's label.

The warning letter also accuses the doctor under contract with Merck and company sales representatives of minimizing the risk of bleeding when Vioxx is taken along with Coumadin, a blood-thinning drug. And it says that the doctor promoted Vioxx for unapproved uses and doses and made unsubstantiated claims of superiority to other NSAIDs.

Reuters
September 25, 2001

MERCK SLIPS AFTER FDA SCOLDING ON VIOXX SAFETY CLAIM

Shares of Merck & Co. fell on Tuesday after U.S. regulators accused the firm of making unsubstantiated claims about its hot-selling arthritis drug Vioxx and downplaying a possible risk of heart attack from taking the medicine.

Shares of Merck closed down $1.54 to $62.45, or 2.4 percent, on the New York Stock Exchange - bucking a moderate upturn for other large U.S. drugmakers.

The Food and Drug Administration, in a warning letter sent Sept. 17 and publicized late Monday, ordered Merck to stop using some promotional materials and to send a letter to healthcare providers to correct any false impressions about Vioxx.

The FDA said the promotions minimized results of Merck's so-called VIGOR trial that showed a higher rate of heart attacks among people treated for rheumatoid arthritis with Vioxx, compared with patients taking an older pain reliever called naproxen.

According to the FDA letter, a doctor hired by Merck argued during an audio conference that naproxen protected the heart, which explained why naproxen patients had fewer heart attacks than Vioxx patients. The FDA said that reasoning was "hypothetical."

More than twice as many patients on Vioxx in the trial had had clot-related events, like heart attacks and strokes, than those taking naproxen.

Merck for the past year has insisted that Vioxx did not itself increase the chance of heart attacks in the trial. Instead, it said naproxen itself protects the heart by helping prevent blood clots.

But several noted cardiologists, including Eric Topol of the Cleveland Clinic, received widespread attention last month with a report suggesting Vioxx and rival arthritis drug Celebrex, sold by Pharmacia Corp. , might independently increase the risk of heart attack and stroke by themselves causing blood clots. Both drugs work by selectively blocking the Cox-2 enzyme linked to inflammation.

The researchers urged Merck and Pharmacia to conduct large trials to definitively prove the cardiovascular safety of their drugs, an expensive proposition that the drugmakers say they are considering.

"Merck may have no choice but to do another (safety) study," UBS Warburg analyst Jeffrey Chaffkin said in a research report on Tuesday, following the FDA's warning letter to Merck. He said the clinical data on the cardiovascular safety of Vioxx "are simply not definitive."

Chaffkin said sales of Vioxx and Celebrex have both been hurt in recent weeks by widespread publicity in the wake of Topol's report, which was published in the Journal of the American Medical Association.

Merck spokeswoman Eve Slater on Tuesday said her company was still mulling whether to conduct a giant study to test the cardiovascular safety of two-year-old Vioxx, which is expected to have global sales in 2001 of $3 billion.

"The question is how to design such a study. It would be a massive undertaking that could involve tens of thousands of patients," Slater said.

Shares of Pharmacia closed up 26 cents to $37.86 on the New York Stock Exchange.

American Health Line
September 25, 2001

VIOXX: FDA WARNS MERCK ABOUT 'MISLEADING' ADS

On Sept. 17, the FDA sent a warning letter to Merck & Co. "chid[ing]" the drug maker for "improper marketing" of its "blockbuster" arthritis drug Vioxx, the Wall Street Journal reports. The FDA, which warned Merck about similar practices in February, says the pharmaceutical company "misrepresented" the drug's potential cardiovascular health risks in its marketing campaign, targeted at physicians through "audio conferences, a news release and statements made at medical conferences." Specifically, the letter cites Merck for "glossing over" a possible increased rate of heart problems among patients taking Vioxx compared to those taking other nonsteroidal anti-inflammatory drugs (Adams, Wall Street Journal, 9/25). USA Today reports that in a clinical trial of 4,000 patients, researchers found that those taking Vioxx were "more than twice as likely" to suffer a "serious cardiovascular complication" as those taking the NSAID naproxen.

Merck's marketing campaign has attributed those results to the "protective effect" of naproxen, implying that because naproxen can help prevent cardiovascular problems, it makes Vioxx's rate of heart problems appear artificially higher (Rubin, USA Today, 9/25). In the warning letter, the FDA says, "In fact, the situation is not at all clear" and adds that "no adequate and well-controlled studies" exist to support Merck's theory. The letter also says the drug maker neglected to properly emphasize a potentially "serious" risk of severe bleeding caused by taking Vioxx in conjunction with warfarin, a

medicine used to treat blood clots. The letter informs Merck that it must "develop a plan to immediately cease" its "particularly troublesome" promotional activities and send a letter to health care providers "exposed" to the "misleading" materials (Wall Street Journal, 9/25). The eight-page letter, sent to Merck president and CEO Raymond Gilmartin, is one of "fewer than a dozen" warning letters sent by the FDA this year, USA Today reports. The FDA has set Oct. 1 as a deadline for a response from the company. In the meantime, Merck spokesperson Chris Fanelle said, "We continue to stand by the overall and cardiovascular safety of the product" (USA Today, 9/25).

Associated Press
September 25, 2001

FDA SAYS MERCK MISLEADING ON VIOXX SAFETY

The government has ordered Merck & Co. to cease promotions aimed to get doctors to prescribe its blockbuster arthritis painkiller Vioxx, saying they minimize potential safety risks.

The Food and Drug Administration told Merck to set the record straight by sending a "Dear Doctor" letter to all health workers who may have been exposed to the misleading campaign.

Merck has until Oct. 1 to respond.

The main issue: Whether Vioxx users face an increased risk of heart attacks and strokes. A recent study comparing Vioxx to another painkiller, naproxen, suggested they do. Many heart experts are divided about the risk and want more research. But an FDA advisory panel has said Vioxx should carry a warning label about the potential risk.

Merck has argued that Vioxx falsely looked risky because naproxen thins the blood much like aspirin does and thus protected against heart attacks. It aired that view in the recent promotions that state, "Vioxx is a wonderful, effective" painkiller but not one that has a blood-thinning side benefit.

"In fact, the situation is not at all clear," the FDA responded, saying no studies prove naproxen thins blood enough to explain the discrepancy.

"The company continues to stand behind the overall safety and cardiovascular safety of Vioxx," said Merck spokeswoman Jan Weiner.

Shares of Merck were off $2.02 to $61.97 in afternoon trading on the New York Stock Exchange.

Wall Street Journal
September 25, 2001

FDA WARNS MERCK FOR VIOXX PROMOTIONS

BYLINE: CHRIS ADAMS, STAFF REPORTER OF THE WALL STREET JOURNAL

Federal regulators warned Merck & Co. for improper marketing of its blockbuster arthritis drug Vioxx, saying the company had misrepresented the drug's safety profile and minimized its potential risks.

The Food and Drug Administration, in a Sept. 17 warning letter, chided Merck for its efforts to promote Vioxx to health professionals, which included audio conferences, a news release and statements made at medical conferences. FDA officials said the actions were "particularly troublesome" because the agency had previously objected to promotional material that it said also misrepresented Vioxx's safety profile.

While the FDA sends out dozens of routine citations annually, it issues only a handful of these more-serious warning letters each year. The agency cited Merck for glossing over what might be a higher rate of heart problems among patients taking Vioxx when compared with those on another medication, as well as a risk of bleeding for patients taking the drug in addition to another widely prescribed medicine.

Among other things, the agency told Merck to develop a plan to immediately cease the activities it cited, as well as to send what's typically known as a "dear doctor" letter to all healthcare providers who were or may have been exposed to the misleading promotions. The letter has to be reviewed by the FDA and is

intended to correct the false or misleading information Merck distributed.

Merck's Vioxx is waging a bitter battle with Celebrex, a similar arthritis drug co-marketed by Pfizer Inc., of New York, and Pharmacia Corp., of Peapack, N.J. Both had amazingly successful drug launches in 1999 and quickly became staples in many medicine cabinets. But in the midst of trying to attract patients and their prescribing doctors, the marketers of both drugs have been cited by FDA officials for going too far. Vioxx is expected to bring Merck $3 billion in sales this year and is crucial to the company as it weathers a period of patent expirations — and steep sales declines — of some major drugs.

A Merck spokesman, Greg Reaves, said the company would have no comment on the specifics of the recent letter until it had responded first to the FDA. However, Mr. Reaves did say that, "We continue to stand behind the overall and cardiovascular safety profile of Vioxx."

The FDA's most recent concerns deal with a major clinical trial in which a higher rate of heart problems was observed in Vioxx patients than in patients on a more traditional nonsteroidal anti-inflammatory drug, naproxen. The FDA said that the exact reason for the increased rate of heart problems isn't known, but that the Merck promotional campaign "selectively" presented the hypothetical explanation that drugs used in comparisons with Vioxx help prevent heart problems-thus making Vioxx's rate of heart problems appear to be artificially inflated.

The FDA says that, "In fact, the situation is not at all clear" and that there are "no adequate and well-controlled studies" to support Merck's assertion.

The agency also cites Merck for "minimizing the potentially serious risk of significant bleeding that can result from using Vioxx" and warfarin, a blood-clot medicine, at the same time.

New York Times
September 26, 2001

NATIONAL BRIEFING SCIENCE AND HEALTH: U.S. WARNS MERCK ABOUT MARKETING ARTHRITIS DRUG

BYLINE: AP

The Food and Drug Administration has ordered Merck & Company to cease promotions intended to persuade doctors to prescribe its arthritis painkiller Vioxx, saying the promotions minimize potential risks.

Merck has until Oct. 1 to respond. A recent study comparing Vioxx to another painkiller, naproxen, suggested that Vioxx users faced an increased risk of heart attacks and strokes, but many heart experts want more research. Still, an F.D.A. advisory panel has said Vioxx should carry a warning label about the potential risk.

URL: http://www.nytimes.com

Deseret News (Salt Lake City)
September 29, 2001

18 UTAHNS SUE PHARMACEUTICAL GIANT OVER VIOXX

BYLINE: BY JENIFER K. NII, DESERET NEWS BUSINESS WRITER

Eighteen Utahns have filed a personal injury lawsuit against pharmaceutical giant Merck & Co., alleging the company misrepresented the risks associated with the prescription drug Vioxx.

The people claim in a lawsuit filed in 3rd District Court Friday they suffered ailments ranging from strokes to heart attacks to death after taking Vioxx. Three of the plaintiffs are heirs of a Utah woman who suffered fatal heart problems.

"Defendant misrepresented that Vioxx was a safe and effective way to relieve osteoarthritis, management of acute pain in adults, and treatment of menstrual pain, when in fact the drug causes serious medical problems such as an increased risk of cardiovascular events, including strokes, heart attacks and death," the lawsuit states.

Stephen G. Morgan, the attorney representing the 18 people, said he wasn't aware of any other Vioxx-related lawsuits filed against Merck in Utah. However, he said his firm is working with a California firm that has filed an individual and class-action suit against the company. That firm has associations with similar actions in Arizona, Colorado, Nevada and Wisconsin, Morgan said.

The Utah plaintiffs responded to an advertisement placed in local newspapers earlier this month, Morgan said. They are seeking "reasonable damages."

The lawsuit came on the heels of a government order handed down this week, compelling Merck to stop advertisements and promotions aimed at getting doctors to prescribe Vioxx. The FDA said the promotions minimize potential safety risks.

However, Merck has argued that Vioxx falsely looked risky because naproxen — another painkiller with which Vioxx has been compared — thins the blood much like aspirin does and thus protected against heart attacks. It aired that view in the recent promotions that state, "Vioxx is a wonderful, effective" painkiller but not one that has a blood-thinning side benefit.

"In fact, the situation is not at all clear," the FDA responded, saying no studies prove naproxen thins blood enough to explain the discrepancy.

"The company continues to stand behind the overall safety and cardiovascular safety of Vioxx," said Merck spokeswoman Jan Weiner.

Contributing: The Associated Press

E-mail: jnii@desnews.com

Associated Press
October 3, 2001

UTAH RESIDENTS SUING ARTHRITIS-DRUG MAKER

More than a dozen Utah residents are suing a drug company for allegedly downplaying the health risks of an arthritis drug they say triggers heart attacks and strokes.

The lawsuits against Merck & Co., filed individually last week in Salt Lake City but listed on the same petition for a jury trial, are seeking damages for injuries - and one death - suffered by patients prescribed with Vioxx.

Plaintiffs' attorney Stephen Morgan said the 16-plaintiff filing makes it easier to examine each injury claim on its own merits.

"A class-action is too unwieldy at this point," Morgan said. "But we may well add to the original filing."

Gregory Reaves, a spokesman for New Jersey-based Merck, said Tuesday the company had not seen the lawsuit and refused comment.

At issue is a widely reported research finding that Vioxx may be linked to an increase in the risk of cardiovascular problems such as heart attack, stroke and angina, severe chest pains caused by an oxygen-starved heart.

Many critics say the findings are flawed because the Journal of the American Medical Association study was a compilation of earlier studies that didn't address the cardiovascular-risk questions surrounding Vioxx.

Still, the JAMA study led the Food and Drug Administration to order Merck to cease promotions aimed at getting doctors to prescribe the top-selling Vioxx because the ads played down the drug's safety risks.

Merck has stood by the safety of the arthritis painkiller.

The Utah lawsuits are based on claims by five heart-attack survivors, nine stroke survivors and two people who claim serious health problems resulted from taking Vioxx without the proper warnings. One Utah woman named as a plaintiff is an heir of an out-of-state woman who died after taking Vioxx and undergoing heart surgery.

New York Times
October 9, 2001

THE DOCTOR'S WORLD; FOR PAIN RELIEVER, QUESTIONS OF RISK REMAIN UNRESOLVED

BYLINE: GINA KOLATA

The prescription pain relievers Vioxx and Celebrex surged onto the scene two years ago with an unprecedented marketing effort by their makers and an avalanche of sales. Patients demanded the drugs. And doctors took out their prescription pads, often not even trying to dissuade people who would have done just as well with a cheap alternative, like acetaminophen or aspirin.

Tens of millions of prescriptions have been written, and the drugs remain wildly popular. But now there are troubling questions about whether Vioxx may have an unexpected side effect — a very slight increase in the risk of heart attack.

The risk is hypothesized, not proved; it was suggested in a single Vioxx study and not in studies of Celebrex. And even one of the researchers who is most worried, Dr. Eric Topol, a heart disease expert at the Cleveland Clinic, said, "We are not talking about big risks here." He added that his analysis showed that both Vioxx and Celebrex might increase the risk of heart attacks by 0.3 percent to 0.5 percent a year. That number may seem small, but with millions of people taking the drugs, even a small increase means "you've got a lot of heart attacks on your hands," he said.

In interviews, leading arthritis specialists who have no financial ties to Merck, the maker of Vioxx, or

Pharmacia, which makes Celebrex, say that they are not concerned and that they prescribe the drugs for patients who may have heart disease.

But the Food and Drug Administration recently sent Merck a warning letter, telling the company that its marketing campaigns had to discuss the possibility that Vioxx might increase the risk of heart attacks. And some heart specialists say they are now telling patients that they may want to consider taking other drugs for pain.

At issue is the subtle question of what counts as evidence. The new drugs, known as cox-2 inhibitors, were developed because scientists had discovered a way to make a drug that could alleviate pain and inflammation like aspirin, ibuprofen and naproxen, but without their tendency to cause stomach pain, bleeding or ulcers in a small percentage of people.

Huge clinical trials involving thousands of arthritis patients — the principal intended users of the new drugs -- showed that the drugs performed as expected. They were as effective in relieving inflammation as aspirin and the other nonsteroidal anti-inflammmatory drugs available over the counter. And the incidence of stomach ulcers and their complications plummeted.

But a few years ago, Dr. Garret FitzGerald, a University of Pennsylvania scientist, raised a theoretical question: can cox-2 inhibitors shift a biochemical balance so that blood will be more likely to clot? If so, patients taking cox-2 inhibitors may be at greater risk for heart attacks and strokes.

As a consequence, said Dr. Edward Scolnick, the president of Merck Research Laboratories, the company decided to look specifically for excess heart attacks and strokes in a new study it was designing.

The study, known as Vigor, involved 8,000 rheumatoid arthritis patients who were randomly assigned to take Vioxx or naproxen. Its main objective was to look for gastrointestinal side effects. It found that patients taking Vioxx had less than half the incidence of these disorders — 2.09 percent had the complications, compared with 4.49 percent of patients taking naproxen.

But the study also found that the patients taking naproxen had just one quarter the number of heart attacks of those taking Vioxx. Twenty Vioxx patients, 0.5 percent, had heart attacks, compared with four, or 0.1 percent who took naproxen.

"There are two possible interpretations," Dr. Scolnick said. "Naproxen lowers the heart attack rate, or Vioxx raises it." Either cox-2 inhibitors shift the clotting balance, or naproxen, which can impede blood clotting, has a protective effect.

And so, while the company announced the heart attack findings to doctors and the public, it looked back at its data from studies using different drugs or dummy pills in comparison to Vioxx. It found no evidence that Vioxx increased the risk of heart attacks, Dr. Scolnick said.

He said the company decided that "the likeliest interpretation of the data is that naproxen lowered lowered the thrombotic event rate," meaning that it protected patients from heart attacks. He added that without the theoretical question raised by Dr. Fitzgerald, "no one would have a question remaining in their mind that their might be an additional interpretation."

On the other hand, Dr. Scolnick said, now that the clotting question has been raised, none of the findings to

date are enough to prove that the issue is fully resolved. That lack of proof is why the F.D.A. demanded that Merck explain both sides of the hypothesis, telling doctors and patients that it is not known whether naproxen protects against heart attacks or Vioxx makes them more likely.

In the meantime, Dr. Geis, the group vice president for clinical research of Pharmacia, said his company's drug, Celebrex, was getting tarred with the same brush. Pharmacia's studies never showed any increase in heart attacks or strokes in patients taking Celebrex, he said.

"We say, you must look at the data with the individual drugs and not make a sweeping statement about all cox-2 inhibitors," Dr. Geis said. He added that the company constantly heard from doctors and patients who were worried that Celebrex caused heart disease. And, he said, every time he addresses a medical meeting, he is asked about it. In question-and-answer sessions after his talks, he said, someone always says, "Tell us about the cardiovascular effects."

Usually, Dr. Geis said, he has already discussed the data in his talk, but he does so again.

"We systematically go through our data," he said, and he carefully explains again that the Celebrex studies found no such effect.

Dr. Topol, the heart disease researcher, said his analyses of the data on Celebrex and Vioxx indicated that the drugs might be making blood more likely to clot and so might slightly increase the risk for a heart attack.

All of his patients already have heart disease, he said. And, he added, "We don't have a clue to what we should be doing in patients with heart disease." He tells them to take other drugs for pain if they can tolerate them. And,

he said, someone — Merck or Pharmacia or the federal government — should conduct a study in patients with heart disease to find out conclusively if the cox-2 inhibitors increase heart disease risk.

Some leading doctors who treat arthritis patients are less concerned. "By and large, the drugs are very helpful," said Dr. Michael Lockshin, who directs the Barbara Volcker Center for Women and Rheumatic Disease at the Weill Medical College of Cornell University. Dr. Lockshin does not consult for and is not on the speaker's bureau of Merck or Pharmacia.

While most patients can safely take drugs like aspirin, he added, it is impossible to predict ahead of time who will have problems with gastrointestinal bleeding, and so the cox-2 inhibitors are useful because, he said, they give doctors and patients, "a freedom from that concern."

Dr. John Sergent, an arthritis expert who is chief medical officer at Vanderbilt medical school, also continues to prescribe Vioxx and Celebrex and, like Dr. Lockshin, has not even suggested to Vioxx patients that they switch to Celebrex. He too is neither a consultant nor a member of the speaker's board for Merck or Pharmacia.

Doctors say that even though some patients worry about cox-2 inhibitors, many people continue to ask for the drugs. And doctors tend to comply, even when they suspect that the patients would do just as well with a cheap, over-the-counter pain reliever. Dr. Lockshin, for example, said about half of his arthritis patients who took nonsteroidal anti-inflammatory drugs took cox-2 inhibitors. "That's as much due to public pressure as to

my desires," he said. "They come in all the time and ask for them," he said.

Dr. Sergent has the same experience. "We have a lot of people who don't have contraindications to the standard drugs and who get cox-2 inhibitors," he said. "If someone comes in and says, 'My friend is on Vioxx and I took some of it and it made me feel great,' I may not go to the trouble of suggesting they take naproxen first," he said.

And, Dr. Sergent added, doctors and patients tend to expect that an office visit will lead to a prescription. "To go to a doctor, pay for a consultation, get X-rays, and then have the doctor say, 'What you need are six acetaminophen a day,' is sort of a downer for both the doctor and the patient," Dr. Sergent said.

URL: http://www.nytimes.com

Supreme Court, U.S.
FILED
AUG 10 2009
OFFICE OF THE CLERK

No. 08-905

In the Supreme Court of the United States

MERCK & CO., INC., ET AL., PETITIONERS

v.

RICHARD REYNOLDS, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

JOINT APPENDIX
(VOLUME 2; PAGES 508-1039)

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PETITION FOR A WRIT OF CERTIORARI FILED: JANUARY 15, 2009
CERTIORARI GRANTED: MAY 26, 2009

PHARMACEUTICAL INDUSTRY: MERCK'S VIGOR TRIAL CONFIRMS VIOXX'S GI SAFETY
JPMorgan Americas
Carl J. Seiden
03/28/00 09:54 AM

March 28, 2000

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Pharmaceutical Industry

MERCK'S VIGOR TRIAL CONFIRMS VIOXX'S G.I. SAFETY (WITH A SLIGHT CARDIOVASCULAR WRINKLE)

Company	Ticker	Rating	Price (3/27/00)	52-Wk Range	Earnings 1999	Per 2000E	Share 2001E
Merck & Co.	MRK	MP	$61.13	$87-52	$2.45	$2.80	$3.00
Monsanto	MTC	B	$47.36	$56-33	$0.95	$1.25	$1.45
Pfizer	PFE	B	$34.75	$50-30	$0.87	$1.04	$1.22
Pharmacia & Upjohn	PNU	B	$57.00	$66-43	$1.80	$2.05	$2.45
Warner-Lambert	WLA	B	$91.88	$100-61	$1.96	$2.45	$2.80

Company	Price/ 2000E	Earnings 2001E	Div. Yld.	Mkt. Cap. ($B)
Merck & Co.	21.8	20.4	1.9%	141.6
Monsanto	37.9	32.7	0.3%	30.1
Pfizer	33.4	28.5	1.0%	134.5
Pharmacia & Upjohn	27.8	23.3	1.8%	29.6
Warner-Lambert	37.5	32.8	1.0%	78.9

Source: J.P. Morgan Securities Inc. estimates.
JPMS ratings: B=Buy; LTB=Long-Term Buy;
MP=Market Performer; MU=Market Underperformer.

- Merck announced preliminary favorable results today from its outcomes study (VIGOR trial) to demonstrate Vioxx's safety specific to gastric perforations, ulcerations and bleeds (PUBs). Although no statistics were released, the study expectedly confirmed that Vioxx "significantly reduced incidence of serious gastrointestinal events compared to patients treated with naproxen" – a common NSAID.

- Merck plans to submit an sNDA filing based on this data in "the next few months" to win the FDA's approval to remove (or at least significantly modify) the standard NSAID warning from Vioxx's label pertaining to the risk of serious GI events. This schedule appears to be a few months earlier than our prior projection, but still slightly behind the Searle filing (see our March 22, 2000 16 page report: COX-2 Inhibitor Market; Boosting Forecast to $13 Billion by 2004).

- We need to see the actual trial statistics to anticipate the degree of label change or elimination. Resulting label modification may allow for DTC advertising to (unlike today), highlight the comparative GI safety versus NSAIDS.

- The preliminary analyses of the VIGOR trial, however, also showed that "significantly fewer

thromboembolic events [i.e. heart attacks, strokes were observed in patients taking naproxen." versus those taking Vioxx].

- There is substantial clinical evidence to easily support that this is likely due to a beneficial cardiovascular effect of Naproxen, not a risk of Vioxx. Naproxen and other NSAID's (most notably aspirin), block platelet aggregation thereby preventing clotting and the resultant risk of heart attacks and strokes. This is a COX-1 effect, not a COX-2 effect, therefore, none of the COX-2s should offer this cardiovascular benefit. However, a significant statistical difference between the two drug classes (for reduced cardiovascular events) has not been seen in previous studies.

- This might be an issue of controversy worth watching with the FDA. Ultimately, we believe Vioxx will escape damage – the VIGOR trial was designed to show reduced risk of PUBs versus NSAIDs and apparently it has succeeded. However, one can imagine the FDA (or Advisory Committee) ruminating on the tradeoff between lives saved on COX-2s owing to reduced gastric PUBs, versus lives at increased risk due to the lost anti-clotting benefit of NSAIDs. In the real world, this is not an either/or tradeoff. Patients with cardiovascular risk can simply take one low dose aspirin (81 mg) daily in addition to their COX-2 therapy. Even though the FDA might permit a label change pertaining to the standard NSAID warning on Vioxx's label (given the favorable results on GI safety from the VIGOR trial), it may also include some caution with regard to higher cardiovascular events relative to those observed with the use of NSAIDs. This outcome may position Vioxx at a marginal disadvantage to Celebrex.

- If this does become an issue, Searle's products may be less exposed. Merck clinical studies of Vioxx have not allowed inclusion of patients taking low dose aspirin (i.e. for the cardiovascular protection benefits); however, most of Searle's studies on Celebrex (including their GI outcomes trial, CLASS) have allowed use of aspirin (estimated at 11%, theoretically those at higher cardiovascular risk). Therefore, it is less likely that Celebrex will show any "significantly" higher cardiovascular risk differences from NSAIDs. The downside for Celebrex, is that due to the inclusion of aspirin users, there may be a slightly higher risk of G.I. events (given the added G.I. risk from the use of low dose aspirin by some Celebrex patients in the trial). However, the aspirin contribution to this should be easy to isolate. In addition, if this issue of concomitant use with aspirin becomes important, only Celebrex has the data to support its safety.

- Results from Celebrex's CLASS trial are expected to be presented at the Digestive Disease Week meeting (May 21-24), and its sNDA submission is expected to be filed in the second quarter.

- As a result of these initial findings from the VIGOR trial, Merck has changed the protocols of its other ongoing studies with Vioxx and MK-663 (Merck's next COX-2 inhibitor compound in development) to allow the addition of low-dose aspirin where appropriate. The addition of low dose aspirin (where required for cardioprotection) was not permitted in any of the Vioxx trials so far.

- We estimate that among PNU/MTC, MRK, and PFE/WLA, it is PNU/MTC that enjoys the greatest potential earnings growth horsepower from their COX-2 franchise. From 2000 to 2004, we project that the COX-

2s will single-handedly drive 12-13% of annual EPS growth for the combined PNU/MTC, 6-7% of the EPS growth for MRK, and 2-3% of the EPS growth for the combined PFE/WLA. We rate MTC, PNU, PFE, and WLA as Buys and we rate MRK a Market Performer.

(J.P. Morgan has acted as lead or co-manager in an offering of securities for MRK, PNU and WLA within the past three years. A director of J. P. Morgan is a director of MRK. The analyst or research associate holds positions in PFE and WLA.)

PHARMACEUTICAL INDUSTRY: CELEBREX CLASS TRIAL CONFIRMS G.I. SAFETY
JPMorgan Americas
Carl J. Seiden
04/17/00 09:23 AM

April 17, 2000

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[Illegible]

Pharmaceutical Industry

Celebrex Class Trial Confirms G.I. Safety
(With A Slight Wrinkle) – No Cardiovascular Risk

CHART OMITTED

HIGHLIGHTS

- In a bit of a surprise, results of the Celebrex (Pharmacia) CLASS trial (on GI events vs. NSAIDs) were presented Sat. night (April 15).

- On a variety of measures, Celebrex showed clear statistical superiority on GI safety versus NSAIDs; however, the primary endpoint was a particularly high hurdle, and on this metric Celebrex narrowly missed statistical separation from NSAIDs.

- This appears to be due to the allowance of background aspirin therapy (for cardiovascular risk reduction) – which poses significant GI risk in its own right and may have clouded the GI difference between Celebrex and NSAIDs. Excluding the aspirin patients (22% of total), there was clear statistical GI-safety superiority for Celebrex.

- Celebrex showed no statistical difference from NSAIDs on any of a variety of cardiovascular risk factors. This contrasts to Merck's Vioxx in the VIGOR study, which did show that Vioxx patients experienced more thromboembolic events (i.e. stroke, heart attack) than NSAID patients. This may have been due to the anti-clotting benefits of NSAIDs and the fact that VIGOR did not allow background aspirin therapy. However, in CLASS, even among patients not taking aspirin, there was no statistical difference between Celebrex and NSAIDs on thromboembolic events.

- Celebrex also showed statistical superiority vs. the NSAIDs on measurements of bleeding, showing less anemia and implying less mucosal injury and less sub-clinical bleeding.

- Celebrex also showed statistical superiority to diclofenac (i.e. Voltaren) in liver safety (all hepatic events) and statistical superiority to Ibuprofen (i.e. Motrin, et al) in kidney safety (i.e. all renal events).

It appears that neither the VIGOR study on Merck's Vioxx (see March 28, 2009 FirstCall note) nor this CLASS study on Celebrex is completely void of controversy. Although no data has been presented on VIGOR, Merck has announced that Vioxx significantly reduced serious GI events (we assume that means statistical significance on all GI endpoints); however, Vioxx showed a statistical disadvantage on thromboembolic events. While Celebrex showed no disadvantage on thromboembolic events, it narrowly failed to show statistical significance on the primary GI endpoint, while it did demonstrate statistical advantage on a variety of other GI endpoints. In our view, the Celebrex "controversy" is of less concern as the ability to exclude the aspirin-using population, and then clearly demonstrate statistical GI superiority offers compelling evidence that this is an "aspirin issue". For Vioxx, although medical intuition implies the thromboembolic event issue is an "NSAID-issue," the theoretical cardiovascular protective benefits of Naprosyn (the VIGOR comparitor NSAID) have cut been clinically proven, and the non-aspirin using cut of CLASS did not show the same problem for Celebrex. In our view, the GI superiority of both Celebrex, and Vioxx is the primary issue and should be evident to the FDA. We expect meaningful modification of the standard NSAID GI warning for both products after these data are reviewed. Although there may be some disappointment in the market on Celebrex's failure on the primary endpoint, we do not expect this to be a significant problem and would view any PHA sell-off as a buying opportunity. PHA enjoys the greatest potential earnings growth horsepower from their COX-2 franchise. We rate PHA, PFE, and Warner Lambert (WLA/$104) as Buys, and we rate MRK a Market Performer.

DETAILS:

In somewhat of a surprise move, summary results of the CLASS trial, the large GI outcomes trial comparing Celebrex to NSAIDs was presented by a lead investigator, Fred Silverstein MD (University of Washington) on Saturday night, April 15 at the American College of Physicians meeting in Philadelphia which we attended. Results from this trial were widely anticipated to first be presented at the Digestive Week Meeting in San Diego on May 21-24.

This trial was designed to prove the GI safety of Celebrex versus NSAIDs by demonstrating a lower incidence of severe GI events. The trial included 8,000 patients: 4,000 patients on Celebrex (dosed 400 mg, two times a day – which is double the RA dose); 2,000 patients on diclofenac (Novartis' Voltaren, dosed 75 mg, two times a day); and 2,000 on ibuprofen (dosed at 800 mg, three times a day). Average age was 59-61 years in the three groups, 72% of the patients had osteoarthritis (OA) and 28% had rheumatoid arthritis (RA); 68-71% were female.

GI Safety: Patients were randomized to one of the three groups described above. Patients with lab tests implying a gastric problem (i.e. anemia) or GI symptom of sufficient suspicion were endoscoped for GI diagnosis. These endoscopies were then blinded and independently categorized by experts first as confirmed "ulcers," and, if more severe "complications" were present were further categorized into three types of complications – perforations, gastric outlet obstructions, or bleeds. Two endpoints used to measure GI safety were patients with (a) "ulcers and complications;" and (b) patients only with the more severe "complications." "Complications" are an especially tough clinical hurdle to show superiority on

because of trial design. This is because patients with an "ulcer" that do not have "complications" are removed from the trial and therefore unable to progress to "complications". In addition, patients were allowed in this trial even if they were taking low dose aspirin (defined as up to 325-mg daily) for cardiovascular risk reduction. However, aspirin carries a GI risk of its own, in fact, though data were not presented we were told the risk of aspirin therapy alone appeared equivalent to the risk of NSAID therapy alone. The effect of aspirin on the trial may have been greater than anticipated. In addition, 10-12% of patients were initially expected to be on aspirin – the actual figure was 22%. Table 1 below shows the results on GI outcomes. For the endpoint "ulcers and complications" – Celebrex was statistically superior, both in the group including background aspirin therapy and when those patients are excluded. However, for the higher hurdle, "complications" only, Celebrex was only statistically superior when the aspirin takers were excluded, narrowly missing statistical significance ($p=0.09$ v. the required $p=0.05$) among the study's total population. Unfortunately, this was the predefined "primary endpoint" of the trial.

Table 1: GI Outcome from CLASS Trial

GI Outcome:	Celebrex	NSAIDS	P Value
For all patients:			
Ulcers & Complications	2.0%	3.5%	0.03
Complications	0.7%	1.5%	0.09
Excluding Aspirin patients:			
Ulcers & Complications	1.4%	3.0%	0.02
Complications	0.4%	1.4%	0.037

Source: Fred Silverstein MD Presentation of CLASS Trial Results on 4/15/00.

Cardiovascular Safety: Given the somewhat surprising result in Merck's VIGOR trial with Vioxx showing greater cardiovascular events in the Vioxx group, the issue of Celebrex' cardiovascular safety is of increased importance. Celebrex did not show a statistical difference from NSAIDs on any of the cardiovascular measurements (see Table 2 below). This may have been due to [illegible] high risk patients which were on aspirin (which was not allowed in the Vioxx trial); however, even in the non-aspirin taking CLASS population there was no statistical difference in cardiovascular events. This may be an important advantage for Celebrex.

Table 2: Cardiovascular Outcomes from CLASS Trial*

CV Outcome	Celebrex	Diclofenac	Ibuprofen
Any Myocardial event	1.7%	1.1%	1.3%
Myocardial infarction	0.5%	0.3%	0.5%
Any vascular event	1.4%	1.5%	1.5%
Cerebrovascular events	0.2%	0.5%*	0.5%*
Cardiovascular Deaths	0.3%	0.4%	0.5%

*Indicates statistical difference from Celebrex

Source: Fred Silverstein MD Presentation of CLASS Trial Results on 4/15/00.

Other Outcomes: Possible Celebrex Advantages on Bleeding (vs. both NSAIDs), Kidney (vs. ibuprofen) and

Liver (vs. diclofenac): Table 3 profiles several other safety highlights for Celebrex. Perhaps most surprising are the apparent advantages relative to bleeding risk. Here the endpoint measurement was a decrease in the hematocrit (an anemia measure) of 10 percentage points or more or a decrease in measured hemoglobin of 2 mg/dl. Celebrex was statistically better than the NSAIDs, implying according to Dr. Silverstein less mucosal injury, and possibly less bleeding in the small intestine and bowel. On all hepatic events Celebrex was statistically superior to diclofenac (known to be tough on the liver), and on all renal events Celebrex was statistically superior to ibuprofen (known to be tough on the kidney).

Table 3: Other Outcomes from CLASS Trial*

	Celebrex	Disclofenac	Ibuprofen
"Bleeding" – HCT decrease of 10% or Hgb decrease of 2mg/dl	2.0%	4.5%*	5.0%*
All Hepatic Events (Liver)	1.9%	6.9%*	1.9%
All Renal Events (kidney)	6.5%	6.5%	9.8%*

*Indicates statistical difference from Celebrex

Source: Fred Silverstein MD Presentation of CLASS Trial Results on 4/15/00.

(J.P. Morgan Securities Inc. acted as co– or lead manager in an offering of securities for MRK, PHA, and WLA within the past three years. A director of J. P. Morgan is a director of MRK. The analyst or research associate holds a position in PFE and WLA.)

Merrill Lynch **Global Health Care**
1 May 2000

Global Healthcare Bulletin

* * * [Picture omitted]

Merck Accumulate 4/25/00
Logging a Solid Quarter
(MRK - $69 ¾ - A 2-2-7)

- **Investment Highlights:**

- Merck delivered EPS of 63 cents versus our estimate (and that of the Street) of 62 cents. Merck out performed our estimates below the revenue line. We had anticipated a strong top-line performance as a result of a timing shift on price increases.

- As Merck had stated previously 1Q:00 should be the highest EPS growth quarter for the year. We are therefore comfortable with our estimate of $2.79 for full year 2000. Our rating and estimates for Merck remain unchanged at this time.

- **Fundamental Highlights:**

- The performance of Merck's product portfolio was broad based. Three products Vioxx ($370 million), Prinivil (+55%) and Zocor (+19%) delivered performance in excess of underlying prescription trends. Strong performance was delivered by Fosamax (+20%), Singulair (+89%) and Cozaar (+26%) with Cozaar experiencing a slight buy-out related to Y2K.

- The company has stated that the EPS growth in 1Q:00 should be the highest of any quarter in the year. This is due to movement of the price increases into March from year-end 1999, in order to adjust for possible Y2K effects.

Tighe/Holman

Merck Accumulate 4/27/00
What's Next After Prilosec?
(MRK - $71 15/16 – A-2-2-7)

▪ **Investment Highlights:**

- Several Nexium abstracts have been posted on the Digestive Diseases Weekly (DDW) website in advance of their official presentation at the DDW conference May 21st. Nexium is AstraZeneca's optical isomer of Prilosec.

- Abstracts of two head-to-head trails of Nexium versus Prilosec were released. In one study of patients with erosive esophagitis, 94.1% experienced healing by week 8 with Nexium 40 mg versus 86.9% with Prilosec 20mg. A second study found similar results with 93.7% healing by week 8 with Nexium and 84.2% with Prilosec.

- While these results do not show a large degree of superiority there may be a greater difference when patients with severe disease are singled out. Also, a study sponsored by AstraZeneca revealed a need for improved treatment of all types of heartburn sufferers. In this study of 11,000 heartburn sufferers – of those using Prilosec, only 60.2% were

satisfied with their response. Of those taking Prevacid (a competing proton pump inhibitor) only 51.2.% registered satisfaction. The satisfaction rate dropped to 45.3% for those treated with H2 Blockers such as Pepcid, Zantac or Tagamet.

- This result seems to indicate a need for more effective therapy. The question, however, is whether the degree of improvement seen with Nexium over Prilosec is enough to allow Nexium to maintain and grow share in a market with generic Prilosec.

- Several other abstracts described positive results in (1) preventing relapse of GERD symptoms following successful treatment, (2) chronic therapy of GERD without erosions and (3) therapy in patients with healed erosions.

- Merck currently receives a 32% royalty on Prilosec sales in the U.S. and will receive an estimated 25% royalty on Nexium sales (dropping from 30% initially). Basic Prilosec patent protection in the U.S. expires in October 2001. Litigation involving patents beyond the compound patent is currently ongoing against 4 generic filers including Andrix (the first to file). A victory in this litigation could extend the exclusivity of Prilosec. AstraZeneca anticipates a trial date possibly by year-end 2000 to early 2001.

Table 1: Treatment of Reflux Disease in Patients with Erosive Esophagitis

	Nexium 40mg	Prilosec 20mg	P value
Week 8 Healing (%)	93.7%	84.2%	<0.001

Week 4 Healing (%)	87.7%	68.7%	<0.001

Source: Digestive Diseases Weekly

Table 2: Treatment of Reflux Disease in Patients with Erosive Esophagitis

	Nexium 40mg	Nexium 20mg	Prilosec 20mg
Week 8 Healing (%)	94.1%	89.9%	86.9
Week 4 Healing (%)	75.9%	70.5	64.7%

Source Digestive Diseases Weekly

Tighe/Holman

Merck Accumulate 4/28/00
Vioxx Speculation Seems Overdone
(MRK - $68 5/8 – A-2-2-7)

- **Investment Highlights:**

- Merck stock has reacted negatively to speculation concerning the company's arthritis drug Vioxx. News reports suggested that the FDA may scrutinize the data recently released from the VIGOR study (Merck's GI outcomes study) after an increased rate of cardiovascular events was seen versus the comparator drug Naprosyn.

- Detailed data from the study has not been released. We have no reason to believe that Vioxx would cause a greater rate of cardiovascular events then would be seen without treatment. It may be however that Naprosyn (which is known to inhibit platelet aggregation and thus blood clot formation) reduces the rate of cardiovascular events.

- Unless the incidence of events is higher for Vioxx then placebo (or other NSAIDs) or Vioxx is

suspected of actually causing events then we would not expect the FDA to take issue with the drug.

- The study may simply be reflecting a positive effect of Naprosyn (which may also have a more positive effect then other less potent NSAIDs) rather then a negative effect of Vioxx.

- Our estimates and rating are unchanged.

Tighe/Holman

Goldman Sachs

US Pharma Focus

May 2, 2000

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HIGHLIGHTS

WASHINGTON UPDATE – pg. 2

- **Drug Pricing Takes Center Stage in Washington**
  - Senator Slade Gorton introduces his drug price control bill;
  - Senator Wellstone introduces bill to (illegible) from pharmaceutical companies.
  - President holds another White House drug pricing event with Congressional Democrats.
  - Congressional Democrats announce their intention to unveil a drug pricing bill soon.

COMPANY FOCUS – pg. 2

- **Pharmacia** reports 1Q00 EPS of $0.33 (+27%) in line with consensus. Pharmaceutical sales are $2,845M, up 10% from 1Q99, led by Celebrex sales of $534M.

PRODUCTS IN THE NEWS – pg. 3

- Safety of Merck's Vioxx questioned – Large trial in patients with rheumatoid arthritis shows that naproxen has lower rate of heart attacks than Vioxx.
- Phase II results of ICOS/Lilly impotence drug, **IC351**, to be presented at the American Urological Associate meeting.
- SGP presented data on a Phase III head-to-head trial of PEG-Intron vs. Intron-A, and data on a Phase II head-to-head trial of Peg-Intron plus ribavarin vs. Rebetron at European Association for the Study of The Liver (EASL) meeting.

ON OUR CALENDAR

Date	Event
Apr 29-May 6	American Urological Association, Atlanta
May 2	We expect Ways & Means / Commerce Committees will have drafted Medicare Drug benefit bill; CBO estimates on drug benefit proposal.
May 5-10	American Thoracic Society, Toronto
May 20-23	Amer. Soc. of Ciinical Oncology, New Orleans
May 21-24	Digestive Disease Week, San Diego
May 21-25	American Society for Microbiology, Chicago
Late May	We expect House Committees to mark up their drug benefit bills.
June 10-13	American Diabetes Assoc. San Antonio
June 12-14	Goldman Sachs Healthcare Conference, Dana Point, CA
June	We expect House consideration of and

	vote on Medicare drug bill.
June	Senate Finance Committee will come out with Senate Medicare reform/drug proposal.

FIVE DAY PERFORMANCE

Drug stocks underperformed the S&P 500 during the 5 days ending 4/28, as the group appeared to see profit-taking in the wake of a solid 1Q00 earnings season. BMY led the groups to the upside following its sharp decline in the previous week. PHA lagged the S&P 500 and the group after reporting an in-line quarter, and reports about potential cardiovascular side-effects in the Cox-2 inhibitor class appeared to result in a sell-off in PHA and MRK

Table 1: Absolute & Relative 5-day Performance (04/28/00)

5-day	Absolute	Rel. to SPX	Rel. to Group
BMY	3.9%	1.2%	8.0%
LLY	-0.2%	-2.8%	3.9%
SGP	-1.2%	-3.9%	2.9%
WLA	-3.4%	-6.1%	0.7%
PFE	-3.9%	-6.6%	0.2%
MRK	-6.1%	-8.8%	-2.0%
AHP	-7.2%	-9.8%	-3.1%
PHA	-14.5%	-17.2%	-10.5%
AVG	-4.1%	-6.7%	
SPX	2.7%		

WASHINGTON UPDATE

From Joan Woodward, Washington Analyst

Drug Pricing Takes Center Stage in Washington

Senate and House Democratic leadership announced this week that Congressional Democrats will introduce "in the very near future" legislation to add a prescriptive drug benefit to Medicare. We expect the plan to be very similar to the plan proposed by Clinton last year. The Democratic bill likely will be unveiled next month.

At issue is whether the drug benefit will be tethered to any sort of larger reform. The Senate Finance Committee, which will first consider the matter, is likely to attach a drug benefit to a broader reform. The White House, one adamant about passing a drug benefit only as par of larger reform, seems to be loosening its grip on that idea. House Minority Leader Gephardt said of the drug benefit and reform: "I think you can do them together, or you can do them separately."

Sen. Daschle had a more interesting view on the matter: "The prescription drug benefits are reform." We expect that any drug bill that passes through committee will have superficial reform attached, but will most likely contain more "givebacks" and sweeteners than real reform provisions.

One question on which Clinton and Congressional Democrats have not caved is the universality of the benefit. Republicans will target their proposal toward the lower income brackets, and Clinton and the

Democratic leaders indicated they would not budge on the insistence that the benefit would be universal. Thus, we maintain the unlikelihood of any Medicare drug benefit bill passage before the November election.

Senator Slade Gorton Unveils Drug Pricing Bill

Sen. Slade Gorton (R-WA) introduced a bill this week that would bring foreign drug prices closer in line with those in the U.S. We do not believe this bill will become law. The bill will be referred to the Senate Judiciary Committee, chaired by Sen. Orrin Hatch (R-UT). We believe there is a small chance that the Committee will mark the bill up and report it – Hatch is up for election in the fall and this could be a political win for him. But that is as far as the Gorton bill will get in Congress.

Gorton's bill, The Prescription Drug Fairness Act, would amend the Robinson-Patman Act – which bars companies from discriminating in prices within the United States – to cover overseas sales as well.

Gorton introduced a second, related bill, alongside the first, which would direct the United States Trade Representative (USTR) to monitor drug prices abroad, in order to reduce price disparities. This bill will most likely be referred to the Senate Finance Committee. We do not believe that the bill will move out of that Committee.

Wellstone Bill to Strip Tax Credits From Pharma

Sen. Paul Wellstone (D-MN), introduced a bill this week aimed at the same issues as the Gorton bill. It would strip tax credits from pharmaceutical companies that charged lower prices outside of the U.S., rather than simply threaten companies with non-compliance, as the

Gorton bill would do. The bill is a companion to legislation previously introduced in the House by Rep. Fortney (Pete) Stark, (D-CA). We believe that there is no chance that this bill will move beyond the committee to which it is referred – Wellstone is very liberal, rivaled perhaps only by Kennedy, and Republicans would never give this bill the support it needs to get passed.

At the White House, The Rhetoric Heats Up

The White House has issued their second report on drug pricing this month, this time produced by Families USA, a left-leaning interest group. We do not believe that this report will have any impact on Congress. However, it does provide insight into the shifting dynamic at play in Washington on the issue of pharmaceutical pricing and a drug benefit.

The focus of the report is a set of figures showing that pharmaceutical prices are rising faster than inflation, sometimes much faster. It asserts that drug prices have risen 3.9% in the last year, much higher than the general inflation rate of 2.2%. **We note, however that the most aggressive price increases were taken on generic drugs, which we believe inflated the percentage increase.**

The second point relates to the percentage of total earnings some lower-income seniors spend on drugs. The report estimates that some seniors at 150 or 200 percent of poverty will have to spend 15 percent or more of their income on drugs. The arguments are, for the most part, based on anecdotal evidence, and the document is mainly rhetorical, with iittle factual basis. **More importantly, the statistics are not consistent with Bureau of Labor Statistics figures, produced**

monthly, which indicate that pharmaceutical price growth was in fact lower than PPI for all finished goods.

White House Conf. on Drug Pricing during Summer
We are now hearing that the White House is setting up a "Conference on Drug Pricing" to be held later this summer in the East Room of the White House. We believe election year politics are a major driver here.

The conference will focus on **drug costs and pricing practices.** As the HHS study makes clear, not enough is known about costs and prevalent pricing practices by the pharmaceutical industry. To further the policy debate, HHS in collaboration with the private sector will convene a conference this summer including representatives of beneficiaries, purchasers, pharmacists, pharmaceutical manufacturers and researchers to clarify actual pricing and discounting practices and their impact on Medicare beneficiaries. Topics covered may include:

- **Pricing practices:** What are and what determines the pattern of cash discounts and rebates offered by manufacturers to different customers? To what extent are drug formularies influenced by price and other incentives? How has the growth of third-party pharmacy benefit managers affected the pricing structure of the industry? What explains geographical variations in prescription drug prices?

- **Models**: What are the best purchasing, delivery and quality improvement practices for prescription drugs? What is the best way to ensure continued innovation within the

pharmaceutical industry under a Medicare prescription drug benefit?

Our View: The Families USA report, which is just one of many to come out in recent weeks in Washington on the issue of prescription drugs, illustrates a larger strategy that we believe will play an increasingly important role in this year's election politics.

Republicans have traditionally been opposed to enlarging the Medicare program – they are usually more likely to propose cuts than new benefits. However, this year, political pressures have forced them to take up the issue as their own. What is also interesting is that the GOP is focusing on the low-income portion of the benefit, instead of catering more to their constituency. This is understandable, however, in the light of the fact that a targeted benefit would increase spending less than universal subsidization. This is one of many examples that could be cited of the Republican Party adopting typically Democratic issues as their own.
Democrats, to whom the prescription drug issue has belonged exclusively until late, are abandoning the issue somewhat for a newer one: **drug pricing.** The benefit that many, on either side of the aisle, will see in taking up this issue is that it can be addressed without a great deal of government spending. Democrats have the distinct advantage in this area, however, they are not so intimately tied to drug manufacturers.

Where Sen. Gorton proposes a bill to "monitor" prices of drugs abroad, Congressional Democrats can introduce a bill, like Sen. Wellstone's, which would actually take tax credits away from pharmaceutical companies.

Clinton and the Democrats have found themselves an issue that the Republicans will have a hard time stealing away. **Drug pricing is now the "hot" issue in Washington since the Republicans have taken the drug coverage issue away from the Democrats.**

COMPANY FOCUS

Pharmacia 1Q00 Earning results

Pharmacia reported 1Q00 EPS of $0.33 (+27%) in line with consensus. Total sales grew 6% to $4,287M; pharmaceutical sales grew 10% to $2,845M led by growth in key products:

- Celebrex $534M (+92%)
- Xalatan $161M (+58%)
- Ambien $103M (+15%)
- Detrol $100M (+55%)
- Camptosar $ 80M (+25%)

Key developments in the quarter include the completion of the Monsanto and Pharmacia & Upjohn merger, FDA approval of Zyvox, the company's novel antibiotic for Gram-positive infections (including difficult to treat resistant organisms), and FDA approval for first-line use of Camptosar in treating metastatic colon cancer.

PRODUCTS IN THE NEWS

Safety of Merck's Vioxx Questioned

VIGOR study of rheumatoid arthritis shows a lower rate of heart attacks among patients receiving naproxen compared to Vioxx users (0.1% for naproxen vs. 0.5% for Vioxx). Merck assures that its review of

all completed and ongoing studies of Vioxx fails to find any difference in the incidence of cardiovascular events between Vioxx and other anti-inflammatory drugs (such as naproxen) and placebo. We maintain our 2000 sales estimate of $1.7 billion.

Last month Merck released new finding from its VIGOR trial, Vioxx Gastrointestinal Outcomes Research, which was conducted in 8,000 patients with rheumatoid arthritis. The good news was that compared to patients taking high doses of naproxen, patients receiving Vioxx had a significantly lower rate of ulcers and gastrointestinal events. This is an important finding and one that provides strong evidence that Vioxx, a member of the new class of drugs called COX-2 inhibitors, is much safer than the older class of drugs known as non-steroidal antiinflammatory drugs or NSAIDs. **These data will be submitted to the FDA to support removal of the NSAID class labeling that warns of the potential for GI toxicity.**

What has attracted more attention is the finding that there were significantly fewer thromboembolic events in the naproxen group. While naproxen is known to inhibit platelet aggregation (or "clumping" that can lead to the formation of clots in arteries), it has never been shown clinically that naproxen prevents heart attacks in the way that aspirin, another platelet inhibitor, does. We do not find this lack of data surprising as outcomes studies were never conducted on these older off-patent NSAIDs. It is well known, however, that COX-2 inhibitors do not inhibit platelet aggregation to any significant degree and would not be expected to prevent heart attacks.

Merck has issued some clarifications on the findings:

- Vioxx did not have a significantly higher incidence of stroke in the VIGOR trial;
- Significantly fewer heart attacks were observed among patients receiving naproxen compared to Vioxx (0.5% vs. 0.1%);
- In a review of all completed and ongoing osteoarthritis trials with Vioxx, there is no difference in the incidence of cardiovascular events in patients taking Vioxx vs. other NSAIDs or placebo. Actual rates were not released.

Merck also cited previously released data from the CLASS study comparing Celebrex to ibuprofen and declofenac. In that outcomes study conducted among 8,000 patients with osteoarthritis and rheumatoid arthritis, the rates of heart attack among Celebrex patients was 0.5% compared to 0.3% among diclofenac patients and 0.5% among patients taking ibuprofen. While these rates are similar to the rates with Vioxx, the CLASS study permitted the use of aspirin, which is known to prevent heart attacks. It would be important to know whether the rate of heart attacks is any different among the patients not receiving aspirin.

If a label change were to be considered by the agency, we would not expect either drug, Vioxx or Celebrex, to be given preferential labeling over the other with respect to cardiovascular safety. Since neither Vioxx nor Celebrex inhibit platelet aggregation even at high doses, we would not expect either drug to reduce the incidence of cardiovascular events in patients at risk for heart attacks or stroke. While the FDA has not yet reviewed this issue, we would expect the agency to consider the drugs together as a class because of this similarity between the drugs with regard to their effects

on platelets. **However, we believe the more conclusive GI safety achieved in Merck's VIGOR study could plausibly result in a preferential safety label for Vioxx relative to Celebrex.**

ICOS/Lilly Impotence Drug Preliminary Findings

Preliminary results released on ICOS/Lilly drug IC351 for erectile dysfunction, now in Phase III, are promising. Full details will be released at this week's American Urological Association meeting in Atlanta. The published [illegible] shows rates of successful intercourse to be 93% for patients receiving daily therapy and 70% for those taking therapy on demand. The results for patients receiving placebo, an important piece of information, were not available.

Phase II results of IC351 are being presented at the American Urological Association meeting this week in Atlanta. Summary results were published in abstract form in advance of the meeting. The drug, an inhibitor of phosphodiesterase type 5 similar in action to Viagra, has been studied in two double-blind, placebo-controlled trials. In the studies, patients have received daily doses of IC351 for 3 weeks at doses up to 100 mg or therapy on demand at doses up to 25 mg. Rates of successful intercourse on IC351 were 93% on daily therapy and 70% with on demand therapy; no results were presented on placebo. To provide some context, diary data in two studies of Viagra showed rates of successful intercourse to be 70% for Viagra and 29% for placebo. While not much study detail is available in the abstract (including the number of patients treated), on the surface, these results appear to be promising.

The most common adverse events were headache, back pain, muscle ache, and upset stomach. The incidence of headache was 13-46% of patients receiving daily IC351 compared to 3% in placebo patients and was 3-17% in patients receiving the therapy on demand (compared to 6% on placebo). Fuller results will be presented at the meeting on May 2.

PEG-Intron Data Presented at EAST

SGP presented Phase III data from a head-to-head trial in which PEG-Intron achieved higher rates of sustained virologic response than Intron-A with comparable tolerability – SGP also presented Phase II data from a study of PEG-Intron in combination with ribavarin, which showed that ribavirin enhanced the anti-viral activity of PEG-Intron.

We view PEG-Intron, and subsequently PEG-Rebetron, as important therapeutic advances. The improved dosing convenience of once weekly injections may lead to better compliance and efficacy. However, we believe an improved side effect profile would have been desirable to spur increased use of these drugs. While each new Intron-A iteration is likely to produce better efficacy we expect to cannibalize the predecessor compound, albeit with some margin improvement for SGP. We do not believe PEG-Intron is likely to result in a significant acceleration in SGP's interferon franchise, as pent-up demand from refractory patients has largely been satisfied, and additional demand must come from treatment-naïve hepatitis C patients, many of whom do not seek treatment due to lack of symptoms. We project Intron A/Rebetron franchise sales of $1.6 billion in 2001.

WEEKLY PRESCRIPTION TRENDS

Figure 1: SSRIs New Prescription Market Share

[CHART OMITTED]

Market Share

	3/24/00	3/31/00	4/7/00	4/14/00	4/21/00
Prozac	24.7%	24.8%	24.5%	24.7%	24.5%
Zoloft	25.0%	24.9%	24.9%	24.9%	25.1%
Paxil	24.9%	24.8%	25.0%	24.7%	24.7%
Celexa	11.7%	11.8%	11.9%	12.0%	12.0%

Week-over-Week Change

	3/31/00	4/7/00	4/14/00	4/21/00	4-Week
Prozac	4 bp	-24 bp	16 bp	-21 bp	-25 bp
Zoloft	-5 bp	-2 bp	1 bp	16 bp	11 bp
Paxil	-9 bp	21 bp	-32 bp	-4 bp	-25 bp
Celexa	13 bp	5 bp	13 bp	-5 bp	26 bp

Prozac lost 21 basis points of new prescription market share in the week ended 4/28/00. The four-week market share decline was 25 basis points, which is slightly better than our projection. We expect the general trend of declining market share in a growing market to continue for Prozac.

Figure 2: COX-2 Inhibitors New Prescription Market Share

[CHART OMITTED]

Market Share

	3/24/00	3/31/00	4/7/00	4/14/00	4/21/00
Celebrex	52.7%	52.2%	52.3%	51.7%	51.3%
Vioxx	47.3%	47.8%	47.7%	48.3%	48.7%

Week-over-Week Change

	3/31/00	4/7/00	4/14/00	4/21/00	4-Week
Celebrex	-51 bp	14 bp	-62 bp	-42 bp	-141 bp
Vioxx	51 bp	-14 bp	62 bp	42 bp	141 bp

Vioxx gained 42 basis points of new prescription market share to Celebrex in the most recent week. In the past four weeks, Vioxx has gained 141 bps of market share. We continue to believe that Vioxx is the better of the two products due to once daily dosing and better efficacy and that Vioxx will eventually gain a leading market share. However, we forecast both drugs to garner significant sales in this rapidly expanding market. In fact, if Vioxx repeats its 4-week performance in the next four weeks, its market share would exceed 50%.

Figure 3: Glitazones New Prescription Market Share

[CHART OMITTED]

Market Share

	3/24/00	3/31/00	4/7/00	4/14/00	4/21/00
Rezulin	7.2%	0.1%	0.1%	0.0%	0.0%
Avandia	48.6%	52.6%	53.1%	53.7%	54.3%
Actos	44.2%	47.3%	46.8%	46.2%	45.7%

Week-over-Week Change

	3/31/00	4/7/00	4/14/00	4/21/00	4-Week
Rezulin	-706 bp	-4 bp	-7 bp	0 bp	-717 bp
Avandia	400 bp	55 bp	62 bp	58 bp	575 bp
Actos	306 bp	-51 bp	-55 bp	-58 bp	142 bp

Although Actos has been the best-performing glitazone over the past four weeks, Avandia has gained more market share than Actos in the past three weeks (+517 bps for Avandia vs. +200 bps for Actos). While we believe the lack of LDL elevation seen in Actos may have become a significant competitive advantage for the product, Avandia has performed better than we have expected in the past several weeks. Nevertheless, we continue to believe Actos could drive upside to our EPS projections, and should offset investor worries about potential softness in Prozac, simply as a result of the sooner-than-expected withdrawal of Rezulin from the market.

STOCK PERFORMANCE

We believe that a relative shortage of positive news flow in the wake of a strong earnings season and recent outperformance could result in market performance or underperformance in the near term. While downside risk in the group could result from a return of negative sentiment about Medicare reform, we believe investors have ceased to be concerned by isolated proposals as no resolution of this issue appears likely until after the November election.

The GS US Drug Group currently trades at a 21% premium to the S&P 500 2000E P/E multiple, and the median stock trades at a 14% premium; above the

historical average (since 1982) of a 12% premium. Our favorite remains MRK, at a 5% discount to the S&P 500. We believe recent investor concerns about potential cardiovascular side-effects for Vioxx are unwarranted and that the stock has sold off to especially attractive levels. We expect MRK to have several positive events ahead of it to drive outperformance.

Figure 4: GS US Drug Group P/E vs. S&P 500 (Since 12/31/98)

4 Week	Absolute	Rel. to SPX	Rel. to Group
LLY	28.4%	31.0%	15.2%
WLA	22.5%	25.1%	9.3%
PFE	19.3%	21.9%	6.1%
SGP	17.4%	20.0%	4.2%
MRK	9.7%	12.4%	-3.4%
AHP	7.8%	10.5%	-5.4%
PHA	6.9%	9.5%	-6.3%
BMY	-6.5%	-3.9%	-19.7%
AVG	13.2%	15.8%	
SPX	-2.6%		

12 Week	Absolute	Rel. to SPX	Rel. to Group
AHP	21.1%	16.9%	14.4%
PHA	20.9%	16.7%	14.1%
WLA	20.1%	15.9%	13.4%
LLY	18.9%	14.7%	12.2%
PFE	16.6%	12.4%	9.8%
SGP	-11.1%	-15.3%	-17.9%
MRK	-12.1%	-16.3%	-18.8%
BMY	-20.5%	-24.7%	-27.3%
AVG	6.7%	2.5%	
SPX	4.2%		

Year-to-date	Absolute	Rel. to SPX	Rel. to Group
AHP	42.4%	42.4%	24.3%
PHA	40.0%	40.1%	22.0%
WLA	39.3%	39.4%	21.3%
PFE	28.9%	29.0%	10.9%
LLY	16.4%	16.4%	-1.7%
MRK	0.6%	0.6%	-17.5%
SGP	-3.5%	-3.5%	-21.6%
BMY	-19.8%	-19.7%	-37.8%
AVG	18.0%	18.1%	
SPX	-0.1%		

Table 2: GS US Drug Group Relative Valuation

	AHP		BMY		LLY		MRK		SGP		Group Avg	S&P 500
Rating:	MO		MP		RL		RL		MP			
6/1/00												
Yesterday's Close	55.88		51.50		77.38		67.56		40.[illegible]			1468
52 Week High	64.94		79.25		80.50		81.13		57.44			
52 Week Low	36.50		42.44		54.00		52.00		30.50			
YTD % Price Change	42%		-20%		16%		1%		-4%		18%	0%
Market Cap ($ Billions)	$ 73.0		$ 104.5		$ 86.3		$ 163.4		$ 60			
Dividend Yield	1.6%		1.6%		1.0%		1.6%		2.2%			
Shares Outstanding (Millions)	1,307		2,029		1,115		2,418		1,468			
Earnings Per Share												
1999A (Y-Y%)	1.61	(13)	2.06	15	2.28	18	2.45	14	1.42	20	17	60.82
2000E (Y-Y%)	1.91	19	2.32	13	2.65	16	2.80	14	1.64	15	21	57.58
2001E (Y-Y%)	2.10	9	2.60	12	3.07	16	3.10	11	1.87	14	13	62.92
2002E (Y-Y%)	2.43	16	2.90	11	3.42	12	3.42	10	2.03	9	13	
2003E (Y-Y%)	2.74	13	3.20	11	3.83	12	3.79	11	2.17	7	11	
2004E (Y-Y%)	3.04	11	3.59	9	4.13	8	4.21	11	2.25	3	9	
2005E (Y-Y%)	3.30	9	3.82 9	9	4.37	6	4.72	12	2.31	3	8	
EPS Growth 1999E-2002E (%)		13		11		13		11		10	13	
EPS Growth 1999E-2005E (%)		12		10		11		11		7	11	
P/E												
1999	34.7x		25.0x		34.0x		27.6x		28.8x		37.7x	25.9x
2000E	29.2		22.2		29.2		24.1		25.0		30 8	25.5
2001E	26.7		19.8		25.2		21.8		21.9		27.2	23.3
2002E	23.0		17.8		22.6		19.8		20.2		24.1	
Relative P/E 1999 (S&P, Group)	1.20	0.92	0.87	0.66	1 18	0.80	0 96	0.73	1.00	0.76	1.30	
Relative P/E 2000 (S&P, Group)	1.14	0 96	0.87	0.72	1 15	0.96	0.96	0.78	0.98	0.81	1.21	
Relative P/E 2001 (S&P, Group)	1.14	0.98	0.86	0.73	1.08	0.93	0.93	0.80	0.94	0.80	1 17	
2000E P/E to 3 yr CAGR		2.29		1.96		2.24		2.27		2.52	2.45	
2000E ($Billion% over 1999)												
Total Sales	$ 15.0	0%	$ 6.0	8%	$ 11.2	13%	$ 28.7	18%	$ 10.1	10%	$ 16.3	11%
Pharma Sales	11.1	16	1.8	5	10.5	13	19.8	13	5.5	0	11.4	10
Net Income	2.5	13	4.7	0	3.1	19	6.6	12	2.4	14	3.6	(0)
R&D	1.9	13	6.7	16	2.0	15	2.4	13	1.3	6	2.7	13
SG&A	5.4	11	2.1	11	3.0	10	6.0	16	3.8	9	5.1	11
2000 Percentage Analysis												
Pharma Sales (%Total Sales)	75%		30%		94%		51%		118%		74%	
R&D (%Pharma Sales)	17		378		19		12		12		62	
SG&A (% Total Sales)	36		34		27		16		44		35	
Operating Margin	12		21		34		23		31		23	

Source Goldman Sachs estimates, company reports, and FirstCall.

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MERCK/PHARMACIA: MERCK PRESENTS VIGOR TRIAL AT DDW
JP Morgan Americas
Carl J. Seiden
05/25/00 08:37 AM

May 24, 2000

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Merck & Co. (MARKET PERFORMER)
Pharmacia Corp. (BUY)

Merck Presents Vigor Trial At DDW –
More Numbers, Same Punchlines has been

CHART OMITTED

Highlights

Merck has released more results from the VIGOR trial looking at the GI safety of Vioxx, its COX-2 blockbuster, in a press release this morning and at presentation at Digestive Disease Week, the premier gastroenterology meeting, which we are covering. The

new data adds a little detail to the punchlines, which were initially released several weeks ago.

The VIGOR trial compared Vioxx 50 mg once daily to naproxen (an NSAID) 500 mg twice daily in almost 8,100 patients. On the primary endpoint of GI Perforations, Ulcers or Bleeding (PUBs – in essence "symptomatic ulcers"), the event rate was 2.1% (per year) for Vioxx patients and 4.5% (per year) for naproxen. On the secondary endpoint of Perforations, Obstructions or Bleeding (POBs – in essence "symptomatic ulcers with severe complications"), the event rates was 0.6% per year for Vioxx patients and 1.4% per year for naproxen.

These GI-safety data are remarkably similar to those from the CLASS trial, previously presented for Celebrex (see below). We believe that the results of these two trials effectively demonstrate that the COX-2 inhibitors are safer than traditional NSAIDS.

These trials do not establish that the GI bleeding risk of the COX-2 inhibitors is the same as that of placebo. The extent to which the FDA will modify the product labels of Vioxx and Celebrex (Pharmacia and Pfizer [PFE/$44.19/Buy) on the basis of these two trials is still unknown.]

On cardiovascular safety, the risk of suffering a heart attack among Vioxx patients was 0.4%, versus 0.1% among naproxen patients, a statistically significant increase, which had been previously reported as well. Since there was no placebo arm in this trial, it is impossible to determine if Vioxx patients had an increased risk of suffering heart attacks, or if naproxen patients had a decreased risk.

We believe that for both Vioxx and Celebrex, most physicians already believe that the drugs are safer and that the next level of marketing is to take that message

directly to consumers. The extent to which the claim of safety superiority to NSAIDs can be made in DTC advertisements will be determined by what label modifications are made by the FDA.

We continue to be enthusiastic about the COX-2 inhibitors (total class forecast of $13 billion in 2004). For Merck, Vioxx sales will only partially offset the pain of patient expirations. We project that Pharmacia, on the other hand, will enjoy robust COX-2 driven EPS growth of 20+%. We maintain our Market Performer rating on Merck and our Buy on Pharmacia.

Details

The VIGOR trial compared Vioxx [illegible] mg once-daily to [illegible] an NSAID) 500 mg twice daily in almost 8,100 rheumatoid arthritis patients. On the primary endpoint of GI Perforations, Ulcers or Bleeding (PUBs – in essence "symptomatic ulcers"), the event rate was 2.1% (per year) for Vioxx patients and 4.5% (per year) for naproxen, a statistically significant 54% risk reduction. On the secondary endpoint of Perforations, Obstructions or Bleeding (POBs – in essence "symptomatic ulcers with severe complications"), the event rate was 0.6% per year for Vioxx patients and 1.4% per year for naproxen, a statistically significant 57% risk reduction.

On cardiovascular safety, the risk of suffering a heart attack among Vioxx patients was 0.4%, versus 0.1% among naproxen patients, a statistically significant increase. This increased risk had previously been reported as well. There were no differences in cardiovascular deaths or in the incidence of strokes. It is important to note that since there was no placebo arm in this trial, it is impossible to determine if Vioxx patients

had an increased risk of suffering heart attacks, or if naproxen patients had a decreased risk.

In a post hoc analysis that carries little statistical weight but is comforting, Merck showed that 47% of heart attacks in the trial occurred in the 4% of VIGOR patients with the highest cardiovascular risk. Because this was not a pre-specified analysis, it is not convincing. But if those 4% of patients are excluded from the analysis, the heart attack rate drops to 0.1% for Vioxx and 0.2% for naproxen.

The principal investigator believed that there were no significant differences in the incidence of hypertension or edema. To date, these have been the only meaningful dose-related side effects seen with Vioxx. However, the data were not presented today, nor were they included in Merck's press release.

Overall, the results are remarkably similar to those from the CLASS trial, previously presented for Celebrex (Table 1). Although the patient populations were slightly different (Table 2), these results demonstrate that the COX-2 inhibitors as a class are less likely than NSAIDs to cause GI events. Whether the FDA will consider this evidence powerful enough to remove the NSAID class warning, or to modify it for COX-2 inhibitors, remains to be seen. A further question is whether future Cox-2 inhibitors will need to prove GI safety versus NSAIDs in large trials like VIGOR and CLASS, or will the FDA allow a "COX-2 class label" for these drugs.

Table 1: Summary of Results of the VIGOR and CLASS trials

	VIGOR Trial		CLASS Trial	
	Vioxx	**NSAID**	**CELEBREX**	**NSAIDs**
Non-aspirin patients				
PUBs	2.1%*	4.5%	1.4%*	3.0%
POBs	0.6%*	1.4%	0.4%*	1.4%
Risk of heart attack	0.4%*	0.1%	0.2%	0.1%
Including aspirin patients				
PUBs	n/a	n/a	2.0%*	3.5%
Complications	n/a	n/a	0.7%	1.5%
Risk of heart attack	n/a	n/a	0.5%	0.3-0.5%

Source: JPMS research.
Note: Primary endpoints are bolded. The VIGOR trial excluded patients on aspirin.
*indicates result achieved statistical significance.

Table 2: Comparison of VIGOR and CLASS Patient Populations

	VIGOR	CLASS
Number or Patients	8,076	About 8,000
Breakdown	100%	28%
	Rheumatoid Arthritis	Rheumatoid Arthritis, 72%
		osteoarthritis
Average age	58	59-61
% female	80%	68%-71%
% on aspirin	0%	22%

Source: JPMS research.

In the VIGOR trial, the primary endpoint used to measure GI safety was PUBs, the combination of symptomatic ulcers and complicated GI event (ulcers, perforations, obstructions and bleeding or POBs), and the secondary endpoint was POBs. POBs is a more difficult endpoint because patients in the trial who experience GI symptoms and are evaluated are removed from the trial if they prove to have an ulcer even if one of the other complications, such as bleeding, is not present. Thus, many patients who would be at risk for going on to develop a POB are removed from the trial before having a chance to. By comparison, in the CLASS trial a similar rubric was used to assess safety, but POBs was the primary endpoint and PUBs the secondary endpoint. In addition, of the 8,000 patients in the CLASS trial, about 22% were also taking aspirin, well-known to cause ulcers and GI bleeding. This population was excluded from the VIGOR trial.

For both drugs, the safety trials, while very impressive, also present challenges: for Vioxx, there is the increased risk of heart attacks for patients on Vioxx versus naproxen (probably but not conclusively due to the anti-platelet effect of naproxen); for Celebrex, there is the failure to obtain statistical significance on the primary endpoint (which in CLASS was POBs). Whether either of these issues proves to be important in negotiations with FDA, or proves to be a significant detailing point, remains to be seen.

(J.P. Morgan Securities Inc. acted as co- or lead-manager in an offering of securities for MRK and PHA within the past three years. A director of J.P. Morgan is a director of MRK. The analyst or associate has a position in PFE.)

ABN-AMRO

Pharmacia Corporation
GI Safety Data Mounting for Celebrex, Maintain 20% EPS Growth Outlook

USA Pharmaceuticals NYSE: PHA – $52 – 125
Top Pick
May 26, 2000

Mario V. Corso, CFA **617/951-3216**
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Market Profile

52-Week Range $60 – 33	EPS Growth Rate (3-5 Yrs.) 26%
Avg. Daily Volume 5,272 M	ROAE (LTM) 16.0%
Shares Outstanding 1,286.0 MM	Debt to Total Capital 50%
Market Capitalization 67,033 MM	Book Value Per Share $4.31
Floating Market Cap. 66,362 MM	Indicated Dividend/Yield 0.18/0.35%
Institutional Owner 79%	Revenue (LTM) $16,618 MM
Insider Holdings 1%	

Earning/Share

					Fiscal Year	Calendar Year	Calendar P/E Ratio
	1Q/Mar	2Q/Jun	3Q/Sep	4Q/DEC			
1999	$0.26E	$0.40E	$0.21E	$0.24E	$1.11E	$1.11	47.0x
2000	$0.33A	$0.47E	$0.34E	$0.45E	$1.59E	$1.59	32.8x
2001	-	-	-	-	$1.95E	$1.95	26.7x

Highlights

• At this week's DDW conference, COX-2 GI safety data was discussed, and our main focus was on Celebrex data (with and without concomitant aspirin use), and MRK's Vioxx MI incidence.

• We continue to believe that Celebrex GI safety is evident with and without aspirin use, and we are still somewhat puzzled by a higher incidence of MI with Vioxx use.

• In 2H:00, second generation data and filings are expected to take place, and the new GI safety data could be added to Celebrex/Vioxx labels, although the FDA may not remove the standard NSAID warning label.

• PHA remains our Top Pick in the drug sector with a $72 price target, given its outlook for reinforcements to its mains pharma growth drivers, and our belief that agriculture concerns are of relatively small importance on the bottom line.

Reason for note: COX-2 Data At DDW Conference

At this week's Digestive Disease Week Conference, PHA and MRK presented data and held symposia on their Cox-2 inhibitor drugs, Celebrex and Vioxx, for the treatment of arthritis. As was released in previous press announcements, both drugs demonstrated a beneficial gastrointestinal (GI) side effect profile relative to traditional non-steroidal anti-inflammatory drugs (NSAIDS), such as naproxen, ibuprofen, and diclofenac, in terms of ulcers, perforations, and bleeding. At issue for the Cox-2's in recent weeks has been the lack of primary statistical significance in Celebrex's trial, as well as higher incidence of heart attack (MI) in the Vioxx study relative to its comparator NSAID's.

We continue to believe that Celebrex trial's primary endpoint was confounded by allowing patients to use aspirin concomitantly, and this should not overshadow that the results were significant when the aspirin users (approximately 20%) are removed from the data set. Although the aspirin use is beneficial to patients in terms of cardiovascular protection, it is harmful to the GI system. Stripping out the aspirin use from the Celebrex study puts the trial on par with MRK's Vioxx study, which did not allow aspirin use.

We are puzzled by the Vioxx MI issue, which could draw FDA ire, MRK has argued that the higher MI incidence relative to Naproxen (0.4% vs. 0.01%) is a result of a cardiovascular benefit of naproxen, not due to harmful effects of Vioxx. However, there have not been any clinical studies demonstrating a cardiac benefit of naproxen. Aspirin is a well-known cardio-protectant due to its antiplatelet properties, as is a seldom-used compound related to ibuprofen (less so than aspirin). New data at this week's conference indicated that 4% of

the patients in MRK's trials could be classified as high risk for MI's, and accounted for 47% of the events. In addition, MRK commented that the MI's were not correlated with hypertension, which is important because Vioxx has been associated with a dose dependent elevation in hypertension and edema, which could be associated with MI. In our opinion, the new Vioxx information appears plausible, but the inconsistency remains that in previous Celebrex trials versus Naproxen, there was no increase in MI reported, with or without aspirin use. Plus, in the recent GI safety studies, when aspirin use was removed from Celebrex data, the product and its comparator NSAID's, ibuprofen and diclofenac, all showed MI incidence in the 0.1-0.2% range, well below the Vioxx rate of 0.4%, and in-line with the naproxen rate of 0.1%. When the aspirin use is included in the Celebrex data, the incidence rises to the 0.3-0.5% range, most likely due to aspirin users being high risk patients, who ultimately suffered more MI's. Thus we are not convinced that this will be an open and shut case when the FDA reviews the data when it is filed this quarter.

Both companies are expected to file their GI safety data with the FDA this quarter, which we believe could amend product labels as early as 2H:00. However, given the cautious stance of the FDA in recent months, the agency may not remove the standard NSAID GI safety warning from the Cox-2 labels. Rather, the agency may opt to simply add the new safety data to the products' labeling. Either way, we envision use of the Cox-2 class of drugs expanding beyond the current approximately 32% of total prescriptions according to IMS data, which could value the market at $10B + in Cox-2 dollars, while Celebrex and Vioxx currently annualize at a combined level of approximately $3.5B. While weekly new RX's

still favor Celebrex 52% to 48%, and TRX's 55% to 45%, MRK's market share gains have slowed considerably this year, after reaching 40% by year end 1999, from a Q2 launch. Although the market clearly has ample room for two players, we believe that PHA's Celebrex marketing can benefit from the Vioxx MI data. There certainly appeared to be sufficient questions on the issue by physicians at DDW, and the FDA has recently been more side effect focused than clinicians. Interestingly, gastroenterologists' comments at the conference indicated that the cardiovascular side effects that led to market removal of JNJ's Propulsid were so rare that they were virtually non-existent in individual practices, but the FDA acted anyway.

Also of note in the COX-2 market should be data from second generation compounds and potential FDA filings in 2H: 00. Although very little is known about MK-663 for MRK and valdecoxib from PHA, we understand that MRK is focusing studies on chronic arthritis use, rather than on shorter term pain usage. Therefore, the company may eventually focus Vioxx on the pain usage, and market the drugs side by side to different populations and customers, as it does in hypertension with Vasotec, Prinivil, and Cozaar/Hyzaar. PHA's valdecoxib may be more potent and more COX-2 specific than Celebrex, potentially offering better efficacy and safety. Of note at DDW, a small phase II study of the injectable parecoxib, showed dramatically better safety than the only other I.V. NSAID available, ketorolac, which may help PHA on to hospital formularies with its next COX-2 products.

PHA remains our Top Pick in the drug sector, with a price target of $72. In addition to the strong growth of Celebrex, we look for the Xalatan beta blocker

combination eye drop to be approved by the FDA around July, and the Detrol once/day version in early 2001. In our opinion, PHA's major pharma growth drivers are better positioned than those of its peers, with strong current growth, and second generation/line extensions coming soon to bolster sales growth. In addition, no major products are expected to experience generic competition before 2005-07. Further, we believe that attainment of the company's 20% EPS growth objective in the next 1-2 quarters can provide significant stock price appreciation as the company moves in to the top tier of sector growth, perhaps surpassed only by the PFE/WLA combination. As for the biggest risk in PHA's stock, the agricultural division, we continue to believe that its importance is overemphasized. Agricultural biotech accounts for <10% of the divisions approximately $5B in sales. Plus, with net margins likely in the 5-7% range, the business has a small impact on PHA's bottom line, not more than 20% of total company EPS, although a declining 30% on the top line. The second quarter is seasonally the most important quarter for the ag business, and early signs point to a possible improvement over the disappointing Q1 sales of -3%. In key corn and soybean planting areas, planting began early and is far ahead of last year's pace, with potential record crops forecasted by the USDA. Early dry conditions have also mean too little rain for pre-emergent herbicides to be activated, perhaps benefiting use of post emergents like PHA's Roundup. Weather patterns in the next 4 weeks may dictate additional herbicide applications, as crops need to emerge and become strong enough to withstand herbicides, and farmers incomes will become clearer, which effects their spending levels.

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Equity Research
Pharmaceuticals
February 08, 2001

Merck & Co. (MRK-$82.97) – Neutral
Vioxx Label Change Meeting Update

Data					
Long-term Growth	10%	Last ROE	45.9%	Dividend/Yield	1.4%
Top-Line Growth	14%	S&P 500 P/E	22.0x	Shares Out	2,356
Bottom-Line Growth	10%	Avg Group P/E	27.8x	Market Cap (MM)	$195,477
LT Debt to Tot Cap	31.0%	52-Wk Range	96-52	Book Value	$5.70

Key Points

***Merck's meeting today with an FDA Committee to discuss Vioxx label changes was better than expected given concerns that arose out of Wednesday's FDA meeting for PHA/PFE's Celebrex. However, nothing definitive will occur on Vioxx (or Celebrex) label changes until FDA announces their final decision in an estimated 1-3 months.

***The committee stated their desire to add "what was learned" through the VIGOR study to the Vioxx Label. However, the committee also felt any label additions should directly cite the VIGOR trial data, i.e. Vioxx vs. naproxen comparisons.

***The FDA may add two short statements to Vioxx's label. One statement could mention the improved gastrointestinal side-effect profile of Vioxx versus naproxen, an older anti-inflammatory agent. The other could mention an increased incidence of cardiovascular adverse events when taking 50mg (2x normal dose) of Vioxx compared to naproxen.

***There are two keys to competitive position for Vioxx versus PHA/PFE's Celebrex coming out of this meeting. The first and most important key is whether Celebrex receives an improved GI label to match Vioxx. A further key is the exact wording of a possible cardiovascular warning for Vioxx.

***No change to our current estimates for Vioxx or Merck. Merck shares rebounded from yesterday's sell-off and Pharmacia shares dropped based on the meeting news, as the market became concerned Vioxx may end up with a more competitive label than Celebrex. We remain neutral on Merck shares, due to near-term patent expirations, fewer new products, and the unsustainable high growth of Merck-Medco's impact on Merck pharma sales.

Earnings-Estimates						
	Q1 Mar	Q2 Jun	Q3 Sep	Q4 Dec	Year	P/E Year
2000	$0.63 A	$0.73 A	$0.78 A	$0.75 A	$2.90 A	28.6x
2001	$0.72 E	$0.81 E	$0.85 E	$0.81 E	$3.20	25.9x
2002					$3.51	23.6x

Review of Today's Meeting:

Merck met with the FDA's Arthritis Advisory Committee today to discuss potential label changes for Vioxx, their Cox-2 anti-inflammatory, supported by data from the VIGOR clinical study. The meeting went better than expected, given the diminished expectations resulting from yesterday's FDA meeting to discuss Celebrex label changes taking on a challenging tone. The Vioxx meeting ended with a consensus among the committee that "what was learned" during the VIGOR study should be communicated to the public through a label change. We expect any label changes to refer very specifically and rigidly to VIGOR study results. However, nothing definitive on label changes will occur until the FDA makes their final decision in an estimated 1-3 months. Advisory committee recommendations are not binding on the agency, and circumstances have occurred where the FDA goes against said recommendations.

Discussion during the meeting centered on the following two points:

Gastrointestinal (GI) Adverse Events

Showing reduced levels of serious gastrointestinal adverse events versus naproxen (an older anti-

inflammatory) was the purpose of the VIGOR study. After analyzing the VIGOR data, the committee formed a consensus that Vioxx reduced serious GI AE's when compared to naproxen. The Vioxx arm of VIGOR showed a cumulative incidence of perforations, symptomatic ulcers and bleeds (PUBs), VIGOR's primary endpoint, of 2.08% versus 4.49% for the naproxen arm, a significant relative risk reduction ($p<0.001$) of 54%. The committee appeared to feel Merck should be rewarded for this successful clinical study with an improved label citing the data. However, they also felt that the study was a [illegible] comparison of Vioxx against one traditional anti-inflammatory (naproxen) in one patient population (rheumatoid arthritis patients not taking aspirin). Because of this fact, the committee felt it appropriate that any label changes specifically cite the VIGOR results and patient population and not attempt to extrapolate effects to other drugs or patient populations.

Cardiovascular (CV) Adverse Events

An additional, and unexpected relative to general expectations, point of extended discussion was an increase in serious cardiothrombotic adverse events (heart attack, stroke, etc.) seen in the Vioxx arm of the study when compared to naproxen. The cumulative incidence of serious cardiothrombotic adverse events was 1.67% in the Vioxx arm of the study versus 0.70% in the naproxen arm, a significant increase ($p=0.0016$). Merck presented clinical and anecdotal evidence pointing to the cardioprotective effect of naproxen as the cause of this result, citing naproxen's similarity to aspirin, a known cardioprotectant. A meta-analysis of both

VIGOR and previous NDA clinical data also pointed towards naproxen as the "problem", not Vioxx. FDA personnel and some of the committee refuted this hypothesis, noting that naproxen would need to provide a level of cardioprotection higher than aspirin for this hypothesis to be correct. FDA personnel also noted that the higher level of cardiothrombotic AE's for Vioxx were a counterbalance for the reduced gastrointestinal AE's, leading to a similar level of overall safety for Vioxx compared to Naproxen. In our opinion, the committee appeared to recommend a cardiothrombotic warning be added to the label, but that it be a measured warning added only if the gastrointestinal AE benefit is included in order to provide a balanced risk-benefit assessment.

The two scenarios we see as most likely when the FDA makes its final decision are as follows:

Scenario 1: Merck "Wins" – Vioxx Receives Both GI Improvement and CV Warning Statements on Label; Celebrex Receives No GI Improvement Statement on Label

We believe this scenario is somewhere between an advantage to Merck and the maintenance of status quo. Merck will be able to detail superior GI safety for Vioxx to doctors while Pharmacia/Pfizer will be left to counter-detail the negative CV effects of Vioxx as a defense. As the CV warning for Merck becomes weaker, Merck gains relative advantage in this scenario.

Scenario 2: Pharmacia/Pfizer "Wins" – Vioxx Receives Both Statements, but Celebrex Receives GI Improvement Statement on Label

We believe this scenario hurts Merck, as an improved GI safety label becomes a commodity in the Cox-2 class, and Pharmacia/Pfizer can attack Merck's cardiovascular warning.

Given today's action in share prices for Merck and Pharmacia, the market appears to be betting on the former of our two options. This may be due to the fact Merck proved the primary endpoint of VIGOR, while Pharmacia/Pfizer did not do the same for CLASS. We remain neutral on Merck shares, due to near-term patent expirations, fewer new products, and the unsustainable high growth of Merck-Medco's impact on Merck pharma sales.

Our estimates for Vioxx and Merck remain unchanged. Once the FDA makes its final decision and we can assess the competitive position of each product, we will reassess our estimates. Currently, our estimates are as follows:

	WW Sales in Billions		
	2000A	2001E	2002E
Vioxx	$2.16	$3.46	$4.05
etoricoxib			$0.30
Celebrex (PHA)	$2.57	$3.20	$3.60
valdecoxib			$0.50

* - *etoricoxib and valdecoxib are the follow-ups to Vioxx and Celebrex, respectively.*

Companies mentioned:
MRK, PFE, PHA[1]

§ Within the past three years, Bear, Stearns & Co. Inc. or one of its affiliates was the manager (co-manager) of a public offering of securities of this company and/or has performed, or is performing, other banking services, including acting as financial advisor, for which it has received a fee.

SG Cowen **February 9, 2001**
Merck (MRK: $83; Strong Buy)

Slight Positive For MRK as FDA Panel Recommends Changes to Vioxx Label

	EPS FY-Dec	REVISION	C. YR	Q1	Q2	Q3	Q4
2000*	$2.90			$0.63	$0.73	$0.78	$0.75
2001E	3.25	--	26x	0.71	0.82	0.87	0.85
2002E	3.55	--	23	0.78	0.89	.095	0.93

Highlights:

1. FDA Arthritis Advisory Panel Recommends Including VIGOR Data in Vioxx Label, A Significant Plus.
2. Possible Enhanced Cardiovascular Warnings A Negative For Vioxx.
3. Some Panelists Stated That CLASS Data Should Be Included In PHA/PFE's Celebrex Label, But Outlook Is Unclear Given Yesterday's "No" Vote.
4. FDA Action On Label Changes Re: VIGOR And CLASS Expected In Mid 2001.
5. No Change To Our Vioxx Sales Estimates Of $3,330MM In 2001 And $5,500MM In 2004.

Strong underlying trends and a compelling valuation should drive a 12-18 month target price of $92, based on 26x 2002 EPS of $3.55. Tremendous momentum heading into 2001, a few product triggers, and possible sector rotation back into drugs (from which MRK should

benefit disproportionately) justified our strong buy rating.

Questions For FDA Advisory Committee:

1. **Please comment on the differences in cardiovascular event rates between the Vioxx 50 mg and Naproxen groups. Are further studies warranted? Does this finding warrant consumer/prescriber awareness? If so, in what format?**

   Yes (11-0 vote), further studies are warranted. The panelists questioned whether there was a low rate of cardiovascular events in the Naproxen group or high rate in the Vioxx group. The lower rate of cardiovascular events could have been due to Naproxen's cardio-protective effect, lack of cardio-protective effect from Vioxx, or both. Other questions the committee raised include: (1) does Vioxx increase cardiovascular events versus placebo? (2) can we neutralize negative cardiovascular effect by giving low-dose aspirin, without offsetting benefit by reduced GI safety? (3) what level of cardio-protection can be achieved by NSAIDS? These questions require further studies. The committee believed that the findings warrant consumer/provider awareness (10-1 vote). It was suggested that patients at high risk for cardiac event should be given low-dose aspirin concomitantly with Vioxx.

2. **Given the potential effects of concomitant aspirin use on GI and cardiovascular outcomes and the large population of patients for whom both anti-platelet and analgesic/anti-inflammatory agents are indicated, what guidance should be given at this time regarding the concomitant use of aspirin and Vioxx? Are additional studies warranted?**

Panelists noted that clinical judgement for individual patients is needed to balance risk of cardiovascular events with GI safety. Current labeling cites that concomitant use of aspirin with Vioxx may lead to more GI adverse events. The panelists suggested that additional Vioxx/low-dose aspirin studies are warranted (9-2 vote).

3. **Considering the results of the VIGOR trial, do the current NSAID related target organs for toxicity in the current NSAID template remain applicable? (GI, renal/fluid retention, hepatic, and skin).**

GI: Yes (9-2 vote), there should be a change to the GI warning section to include the VIGOR data. Most panelists noted that VIGOR data show decreased GI toxicity for VIOXX-treated patients compared to those who received Naproxen. Two panelists recommended that no change be made to Vioxx's label. The committee also re-discussed the inclusion of the CLASS data in Celebrex's label, although a vote was not taken. Five panelists said it

was appropriate to include the CLASS data in Celebrex's label, specifically Celebrex's superiority to Ibuprofen. Other panelists believed that because the CLASS study did not meet its primary endpoint the data should not be included in Celebrex's label. Separately, one panelist suggested that a class label be created for the coxibs.

Cardiovascular: Yes (10-1 vote), there should be some mention of VIGOR's cardiovascular data. The panelists believed that there was an excess in cardiovascular events in the Vioxx group versus Naproxen, but it is unclear whether the reason is Naproxen's cardio-protective effect or a negative impact from Vioxx.

Other: Other warnings suggested by the committee included stronger language regarding fluid retention in patients with heart failure (no vote taken).

4. **Please comment on the overall safety comparisons between Vioxx and Naproxen in the VIGOR study.**

The panelists believed that in terms of overall safety, Naproxen looked superior to Vioxx.

Additional questions for FDA Advisory Committee:

1. **Do these two large outcome trials suggest that a) GI and b) overall safety should be addressed similarly with large outcome trials before organ specific safety comparison and claims can be considered with new agents in the future?**

   The panelists opined that outcome trials are important, especially if a drug does not have efficacy advantages. One panelist believed that Ibuprofen and Naproxen should be the comparators, and aspirin should be excluded from future coxib trials. Other panelists mentioned that overall safety is more important than organ specific safety, and that serious adverse effects are critical. One panelist noted that drug interactions should be studied at length.

2. **Both the VIGOR and the CLASS studies as well as post-marketing data confirm the high risk for complicated ulcers in elderly patients and in patients with a prior history of ulcer disease. This increased relative risk was seen across all comparators. Current labeling notes these as risk factors. Given that COX-2 selective agents may be regarded by some as having a better GI safety profile, does the current labeling provide adequate awareness for prescribers regarding the increased risks in these populations.**

Most panelists believed that the current label is adequate provided that the cardiovascular labeling is strengthened. One panelist noted that the same factors that increase cardiovascular risk support GI safety. Atherosclerosis causes 50% of deaths in the U.S. The benefit of coxibs is reduced when aspirin is used concomitantly.

Lehman Brothers
Equity Research

United States
April 11, 2001 Health Care
Major Pharmaceuticals
Merck & Co (MRK - $78) 1 – Strong Buy
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Company Update
"Approvable" Letter for Vioxx Safety Label Expansion

Investment Conclusion

- Yesterday, Merck announced the receipt of an "approvable" letter from the FDA for a label expansion for the arthritis drug, Vioxx (rofecoxib).

Summary

- Merck had submitted a sNDA for Vioxx (June 29, 2000) that sought a change in safety claims based on data from a 8,000 patient trial knows as VIGOR.

- The trial demonstrated that Vioxx caused less ulcers than the commonly used NSAID, naproxen.

- An "approvable" letter is issued by the FDA when they intend to give final approval but first require either (a) additional information or data and/or (b) some additional conditions to be met.

- While we do not know what the FDA has requested of MRK, negotiation on the final wording of the label change is likely occurring.

- We feel that this likely label change supports our view that Vioxx will take a superior position to PHA-PFE's Celebrex (celecoxib). We anticipate sales for Vioxx this year to reach $3.5b and $5b in 2002.

EPS (FY 12/31)
2000

	Actual
1Q	0.63
2Q	0.73
3Q	0.78
4Q	0.75
Year	2.90

P/E

EPS (FY 12/31)
2001

	Old	SL Est.
1Q	--E	0.71E
2Q	--E	0.81E
3Q	--E	0.86E
4Q	--E	0.83E
Year	--E	3.21E

P/E

EPS (FY 12/31)
2002

	Old	SL Est.
1Q	--E	0.79E
2Q	--E	0.90E
3Q	--E	0.96E
4Q	--E	0.92E
Year	--E	3.53E

P/E

EPS (FY 12/31)
% change

	2001	2002
1Q	13	--
2Q	--	--
3Q	--	--
4Q	--	--
Year	11	--

Market Data

Market Cap	$182.7B
Shares Outstanding	2,342.9MM
Float	--
Dividend Yield	--
Convertible	Yes
52 wk Range	97 – 62

Financial Summary

Revenue FY01	$49.5B
Five-Year EPS CAGR	11.2
Return on Equity	--
Current BVPS	$4.98
Debt To Capital	11.5%
Disclosure(s)	A

****Stock Overview Chart Omitted****

Rating	Target
New: 1 – Strong Buy	New: $110
Old: 1 – Strong Buy	Old: $110

Market Impact

We expect Vioxx to become the dominant COX-2 inhibitor on the market. Most recently, new prescrip-

tions (NRxs) have been virtually split equally in the U.S. between Vioxx and Celebrex (Celebrex with a slight 20 bps advantage). However, Vioxx has been on a steeper trajectory (30%YoY growth) in NRxs vs. Celebrex (10% YoY). We feel the label expansion for Vioxx, once approved, will cement the #1 position for Vioxx and cause this divergence to be maintained if not increased.

Our forecasts favor this scenario. While we have modest differences in revenues for Vioxx (3.5b) and Celebrex ($3.4b) this year, in 2002 we expect Vioxx to reach nearly $5.0b while Celebrex may generate only $4.1b.

Label Expectations

It is our interpretation from the FDA advisory committee meetings that we attended this past February and yesterday's receipt of the approvable letter, that Vioxx will achieve an expanded label inclusive of its benefit in GI safety over naproxen. This could provide a significant advantage for MRK via:

- Increased marketing ammunition over older NSAIDs and over Celebrex
- Increase formulary acceptance, especially relative to Celebrex

While some language may also go into the precaution section of the label regarding the fact that Vioxx (or perhaps COX-2's in general) is not cardioprotective, we expect that the expanded gastrointestinal safety labeling for Vioxx will be the key.

It is likely that the label expansion for Vioxx will be superior to that of Celebrex. Recall that an FDA advisory committee demonstrated *under*whelming support for a label expansion for Celebrex as it failed to

demonstrate superior GI effects over another NSAID, diclofenac. However, there was superiority over ibuprofen, but only in the combined endpoints of ulcer complications and symptoms of ulcer complications. While the FDA does not necessarily follow the committee's recommendation, it is often a reasonable proxy. Thus, if the FDA chose to include both these data sets, we feel that it would still be an advantage for Vioxx over Celebrex. We anticipate a decision from the FDA on Celebrex at any time. PHA submitted their sNDA June 13, 2001, in advance of MRK.

In summary, should a differentiated label occur for Vioxx over Celebrex, as is our expectation, share split in the arthritis and pain market should surely favor MRK.

Background

We were present at the FDA's Arthritis Drug Advisory Committee Meeting (February 8, 2001), in Gaithersburg, Maryland where a panel of independent medical consultants met to discuss Merck's VIGOR study (Vioxx Gastrointestinal Outcomes Research Study), to determine if any label changes were warranted based on the study's results. The trial consisted of the comparison of Vioxx-treated patients to naproxen-treated patients in a large (n=8,076 rheumatoid arthritis patients), parallel-group, double-blind, multi-center study.

The primary endpoint of the study was a confirmed clinical upper GI event (e.g. gastroduodenal ulcer). The relative risk reduction was 54% (0.46; 95.44% confidence interval of 0.33 – 0.64) lower in patients treated with Vioxx than with naproxen, with a level of significance of $p<0.001$. The relative risk reduction in patients with a more severe confirmed, **complicated** clinical upper GI

event was 57% (0.43; 95% confidence interval of 0.24 - .078) lower in patients treated with Vioxx than with naproxen, with a level of significance of p=0.005.

After considerable discussion, the panel voted in favor (9 to 2) of a label change with respect to GI safety. However, we would expect the change to be narrow. The Panel had a considerable discussion on whether naproxen was representative of all (or most) traditional NSAIDs. It was concluded that it was not, despite its wide spread use in the US, since NSAIDs all have a different selectivity profile for the COX-1 and COX-2 enzymes and hence a differing magnitude of GI side effects. Thus, we expect the label to reflect superiority over naproxen only and **NOT** over all traditional NSAIDs in general. The Panel was careful to point out that ibuprofen (the most commonly prescribed arthritis drug with some 25% of scripts), for example, is thought to be less harmful than naproxen with respect to GI safety.

Additionally, another major topic of discussion with the Panel concerned the increased cardiovascular risk associated with Vioxx use. Specifically, the study results showed that naproxen usage was associated with a 58% lower risk for the development of thrombotic cardiovascular serious events (e.g. heart attack or stroke) compared with Vioxx treated patients. While not statistically significant, there was a negative trend towards Vioxx. While the panel agreed that it was unclear what the source of this increased risk associated with Vioxx usage was due to, the separation between naproxen and Vioxx was deemed significant enough to be highlighted in some context. Thus, the panel voted 10 to 1 in favor of recommending including additional

language in the label pertaining to this increased cardiovascular risk. We expect this additional language to likely be placed in the precaution section and perhaps only in the context of at-risk patients (e.g. patients with a predisposition and/or history of cardiac illness). Additionally, the wording may not isolate Vioxx as much as it might reference the uncertainty of COX-2 inhibitors in increasing thrombotic events. All were in agreement that the topic warranted additional study.

Finally, the Panel discussed at length the overall, or "global", safety of Vioxx as shown by the VIGOR study. There was considerable debate over the risk/benefit of Vioxx, specifically GI benefit verses cardiovascular risk. There was no unanimous conclusion reached on what the overall safety of the study showed. In fact, this question may have provoked the most disagreement among Panel members. Ironically, the Panel voted unanimously over recommending the addition of global safety in the label.

Summary

We want to reiterate our belief that this is a strong positive for Vioxx and MRK. If the GI labeling comes to fruition, this will be the first significant labeling difference between Vioxx and Celebrex (save for perhaps dosing). Although there will be speculation that Celebrex may also ultimately receive a positive GI label change, we assign a very low probability to that occurrence. We maintain our 1 Strong Buy rating on both MRK (based on yesterday's news) and PFE (based on strong sales in other therapeutic areas), with price targets of $110 and $69, respectively.

Company Description: Merck, the third largest pharmaceutical company in the world, derives 60% of revenues from ethical pharmaceuticals, 34% from pharmacy management services, and 6% from animal health.

Trevor M. Polischuk, Ph.D. (1.212.526.1994)
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Related tickers:
PFE - $41.00; 1 – Strong Buy
PHA - $51.20; Not Rated

Goldman Sachs
June 25, 2001

Merck & Co., Inc. (MRK)
MRK(RL): LOWERING GUIDANCE, REITERATE RL

Merck lowered guidance for 2001 and announced that Vioxx sales would be at the lower end of previous forecasts. Gross margins are the key adjustment, we are lowering our gross margins forecast from 40.2% to 39.3% mainly owing to lower Vioxx sales, business mix and foreign exchange. We maintain our Recommended List rating based on compelling valuation (lower multiple than the market) at 21.7 times reduced 2001 EPS of $3.12 (from $3.18). Our new 2002 EPS forecast is $3.40, from $3.51.

Stock data		Price performance	1M	3M	12M
52-week range $94.88-63.63		Absolute	-10%	-3%	-5%
Yield -		Rel to S&P 500	-3%	-12%	11%

Capitalization		Forecasts/valuation	2001E	2002E
Market cap $0.0mn		EPS	$3.12	$3.40
Latest net debt/(cash) -		P/E	21.7	19.9
Free float -		Next quarter EPS	0.78	-
Shares outstanding 2297mn				

Full details

WHAT CHANGED? The EPS guidance range for 2001 was reduced from $3.15-3.25 to $3.12-3.18.

Our new estimate is now $3.12 from $3.18. For the second quarter 2001, new EPS guidance is $0.77-0.79 our estimate is now $0.78, from $0.80. Our new 2002 forecast is now $3.40, from $3.51. We have reduced our 2001 Vioxx estimate from $3.1 billion to $3.0 billion.

BUSINESS AND PRODUCT MIX DEPRESS MARGINS The company has made two adjustments to company wide gross margins in 2001, both negative. The main culprits are Vioxx, business mix, patent expirations, product discounts and foreign exchange.

Large individual product lines can possess significant influence on the overall margins of a pharmaceutical company given the high relative of profitability of individual drugs. Right now, Merck has the misfortune of the slowing of one of its most profitable lines, Vioxx combined with the margin depression associated with profitable products losing patent protection: Vasotec (2000), Prilosec alliance revenues (2001), Pepcid (2001), Mevacor (2001), Prinivil (2002).

Merck has a unique business mix in the industry. We are estimating the company will receive over 50% of revenues from its PBM subsidiary, Merck-Medco in 2001, but Medco will account for only a small fraction of net income. Medco net margins are in the single digits versus 15% for the overall company. As revenues for Medco increase, total company margins decrease, this is a difficult mix to forecast.

The gross margin has a tremendous amount of leverage on Merck's income statement. 100 basis points of gross margins are at least $0.10 of earnings. Merck expects this to be offset somewhat by lower SG&A and R&D growth (with exchange a positive contributor). Several factors have contributed to the margin variability:

- VIOXX: Negative guidance for a high profit product - BUSINESS MIX: Mix shift of Medco and human health.
- PATENT EXPIRATIONS: Losing sales from older products - PRODUCT DISCOUNTS: Discounts for market share - FOREIGN EXCHANGE: Changing Euro environment.

2001 INCOME STATEMENT VARIANCE			MRK	MRK	GS	
Guidance	Guidance	Est	New	Old	New	2Q01 Guidance $0.77-0.79
$0.81 (F/C)	$0.78	EPS Guidance	$3.12-3.18	$3.15-3.25	$3.12	Gross margin 39% 40%
39.3%	SG&A Growth		low single	low dbl	4.0%	dgts dgts R&D Spend
$2.6B	$2.8B	$2.6B	Tax Rate	30.0-30.5%	30.0-30.5%	30.1% Source: Company
Data, GS Research Estimates.						

2001 SALES FORECAST VARIANCE			MRK	MRK	GS	Guidance
Guidance	EST		New	Old	NEW Vioxx	$3.0-3.5B $3.0-3.5B $3.0B
Zocor	$5.8-6.2B	$5.8-6.2B	$6.1B	Fosamax	$1.5-1.7B	$1.5-1.7B $1.6B
Cozaar/Hyzaar	$1.8-2.0B	$1.8-2.0B	$2.0B	Singulair	$1.0-1.2B	$1.0-1.2B $1.3B Medco
$25-26B	$25.26B	$26.0B	Source: Company Data, GS Research Estimates.			

EXPECTED VIOXX WEAKNESS: TROUBLE FOR THE COX-2'S? Merck stated in its release that Vioxx is not expected to reach the high-end of previous guidance ($3-$3.5B) in 2001 because of slower than expected penetration of the COX-2 Inhibitors into the overall pain and arthritis market. The class remains at about 40% of the overall arthritis market.

The Arthritis Panel meeting on February 7th and 8th of this year appeared to shift the focus of the COX-2's from GI benefit versus NSAIDS to overall outcome safety, i.e. with only COX-2 inhibition, does a patient lose the cardioprotective effects of traditional painkiller.

Merck's Vioxx has clearly come under scrutiny owing to the higher rates of heart attack when compared to naproxen seen in the VIGOR study. That said, Merck's data shows no heart attack signal in any placebo-

controlled trial. But in our opinion this could become a perception issue for both drugs.

Changes in the perception of the total benefit of COX-2 inhibition will probably place more scrutiny on the next generation of COX-2's. Celebrex and Vioxx will continue to grow quickly, albeit at more normalized rates.

VALUATION COMPELLING At 21 times our lowered 2001 EPS estimate, Merck is now the cheapest stock in the pharmaceutical industry and trading at a 3% discount to the S&P. We reiterate our Recommended List rating and would recommend purchase at these depressed levels.

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CIBC World Markets *Equity Research*

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Pharmaceuticals

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Merck & Co.

JAMA Study Could Pressure Vioxx: Maintain Hold

Investment Conclusion

- **JAMA Study Negative on Vioxx.** A new study published in the *Journal of the American Medical Association* suggests that patients taking Vioxx, MRK's popular COX-2 inhibitor for arthritis and pain, have a higher incidence of heart attack than the comparator.
- **Study Not Conclusive.** The retrospective analysis of four large studies revealed an incidence of heart attack per year of 0.74% for Vioxx vs. 0.50% for placebo and 0.80% for Celebrex (Pharmacia). However, **the studies were not uniform in comparators (aspirin, NSAIDs), nor did they actually examine a causative effect of COX-2 inhibitors.**

Rating: HOLD	
MRK-NYSE (08/21/01):	$70.75
52-week Range:	$96.68-60.35
Shares Outstanding:	2.3 Billion
Float:	2.3 Billion Shares
Market Capitalization:	$163 Billion
Dividend/Yield:	$1.40/2.0%
Fiscal Year Ends:	December
Book Value:	$6.33 per Share
2001E ROE:	47.0%
LT Debt:	$7.4 Billion
Preferred:	Nil
Common Equity:	$14.9 Billion

Earnings per Share	
2000	$2.90
2001E	$3.16
2002E	$3.50
P/E Ratio	
2000	24.4X
2001E	22.4X
2002E	20.2X

EPS figures diluted.

Company Description

Leading drug company, with 2000 sales of $40 billion. Products include Cozaar and Zocor (cardiovascular), Fosamax (osteoporosis), Vioxx (arthritis) and Singular (asthma). Also owns Medco PBM.

- **Impact on Vioxx.** Growth trends have been pressured as the COX-2 inhibitors (Vioxx, Celebrex) have failed to pick up greater share against conventional arthritis/pain drugs (NSAIDs). The JAMA study falls short of being conclusive but does suggest to us that gaining additional large shares of market against NSAIDs will be difficult.

- **EPS Under Pressure.** With the potential for managed care to use the JAMA study as ammunition against Vioxx, our concern remains EPS vulnerability in 2H01 and 2002, particularly given Medco-related margin weakness. MRK is dependent on Vioxx for EPS visibility, with weakened demand prompting one EPS revision already this year.

- **Maintain Hold Rating.** We are maintaining our 2001 and 2002 EPS estimates of $3.16 and $3.50, respectively. Our Vioxx sales forecast, at the low end of expectations ($3 billion), could be trimmed should trends slow. The shares, trading at parity with the S&P 500, appear appropriate given dampened expectations and potential for further revisions.

Investment Thesis

Our Hold rating on MRK is based on the company's diminished financial flexibility in the wake of patent expirations, higher growth of the lower margin Medco business and resistance to market growth for MRK's COX-2 inhibitor, Vioxx. The largest issue, in our view, is Vioxx, which has enjoyed rapid growth since launch in 1999 (we expect sales of $3 billion this year). However, the class, which includes Vioxx and

Pharmacia/Pfizer's Celebrex, has stalled in terms of market share gains against older drugs (ibuprofen, naproxen, diclofenac), and that has been problematic. As we do not expect much boost from the addition of the VIGOR data on Vioxx's label, further complicated by the JAMA article, or the launch of etoricoxib, a follow-on product slated for NDA (New Drug Application) filing later this year, pressure is likely to remain until new product flow improves. This could occur, we suspect in late 2003/early 2004, with KRP-297, for diabetes, and combination products Zocor/ezetimibe, for elevated cholesterol, and Singulair/Claritin, for allergies. In the interim, however, without acquired or in-licensed products, pressure is likely to remain.

Valuation. Shares of MRK are trading at 20.2X our 2002 EPS estimate of $3.50 vs. 20.1X for the S&P 500. Given EPS visibility issues over the next 12-18 months, we believe that a valuation equivalent to the S&P 500 is likely to persist in the near term.

Pipeline. MRK's substance P antagonist program is moving forward in depression as a product candidate will enter Phase III trials in 3Q01. This is the strongest endorsement of the viability of this program given prior setbacks. However, we do not expect this

program to be completed until late 2003, at the earliest. MRK has an approvable letter outstanding for Vioxx for inclusion of data from the VIGOR trial to be added to the label. The trial demonstrated lower GI (gastrointestinal) bleeding-related adverse event rates in Vioxx-treated patients than in NSAIDs, but also raised questions about the cardiovascular profile. As we expect both these findings to be incorporated into the label, we are not expecting a major trend change. An additional indication for rheumatoid arthritis, filed in early 2001, however, could provide a boost. We expect Invanz, an antibiotic for severe infections, to be approved this year and a filing for etoricoxib, a follow-on COX-2 for osteoarthritis, rheumatoid arthritis and pain, by year end. Other late-stage projects include the Schering-Plough joint venture products, Zocor/ezetimibe and Singulair/Claritin. While we expect these products to be additive to growth, we are not anticipating that they will have enough fire power to fully sustain a higher rate of corporate growth. With both projects in late-stage development, NDAs could be filed within the next 18 months.

Stock prices (as of 8/21/01) of companies mentioned in this report:

Pfizer (PFE-NYSE $40.46, Hold)
Pharmacia (PHA-NYSE $44.16, Hold)
Schering-Plough (SGP-NYSE $38.55, Hold)

Quarterly EPS Estimates

		1 Qtr.	2 Qtr.	3 Qtr.	4 Qtr.	Year
FY 2000	Actual	$0.63	$0.73	$0.78	$0.75	$2.90
FY 2000E	Current	$0.71A	$0.78A	$0.86E	$0.80E	$3.16E
FY 2002	Current	---	--	---	---	$3.50E

Exhibit 1

Merck & Co.: Income Statement by Year

($ in millions, except EPS)

	Year Ended December							
Revenue	**2002E**	**% Chg.**	**2001E**	**% Chg.**	**2000A**	**% Chg.**	**1999A**	**% Chg.**
Pharmaceuticals	$23,600	4.6%	$22,555	11.5%	$20,225	15.7%	$17,480	14.5%
Medco	31,650	20.8	26,200	30.1	20,140	32.2	15,235	31.3
Total sales	$55,250	13.5%	$48,755	20.8%	$40,365	23.4%	$32,715	21.6%
Cost of sales	36,000	17.8	29,716	32.6	22,409	27.8	17,634	25.9
Gross profit	$20,250	6.4%	$19,039	6.0%	$17,956	18.3%	$16,181	17.0%
Gross profit margin	36.7%		39.0%		44.5%		46.4%	
SG&A	6,700	2.1	6,564	5.4	6,228	19.8	5,200	15.3
SG&A/sales	12.1%		13.5%		15.4%		15.9%	
R&D	2,730	8.6	2,515	7.3	2,344	13.3	2,068	13.6
R&D/sales	4.9%		5.2%		5.8%		6.3%	
Operating income	$10,820	8.6%	$9,960	6.1%	$9,384	18.6%	$7,912	19.2%
Operating margin	19.6%		20.4%		23.2%		24.2%	
Interest & other income, net (a)	416	(26.2)	563	27.3	442	(37.5)	707	18.9
Pretax income	$11,236	6.8%	$10,523	7.1%	$9,826	14.0%	$8,620	16.1%
Taxes	3,371	6.8	3,157	5.1	3,002	10.0	2,729	37.2
Tax rate	30.0%		30.0%		30.6%		31.7%	
Net income	$7,865		$7,366	7.5%	$6,824	15.8%	$5,891	12.3%
Net margin	14.2%	6.8%	15.1%		16.9%		18.0%	
Earnings per share, diluted	$3.50	10.5%	$3.16	9.1%	$2.90	18.5%	$2.45	13.9%
Diluted shares outstanding	2,250.0	(5.1)	2,329.0	(1.0)	2,353.2	(2.)	2,407.0	(1.4)

(a) Includes goodwill and net profits (loss) from joint ventures.

Sources: Merck & Co., CIBC World Markets estimates.

Exhibit 2

Merck & Co.: Selected Product Sales by Year

($ in millions)

Revenues:	2002E	% Change	2001E	% Change	2000A	% Change	1999A	% Change
Focus Products								
Zocor	$6,100	1.7%	$6,000	15.6%	$5,280	17.5%	$4,495	13.9%
Cozaar	2,000		2,000	16.6	1,715	23.8	1,385	30.7
Fosamax	1,715	13.6	1,510	18.4	1,275	22.0	1,046	54.8
Singulair	1,630	55.1	1,225	42.4	860	72.0	500	157.7
Vioxx	4,000	33.3	3,000	38.9	2,160	357.6	4.2	NM
Cardiovascular	$10,010	(5.8%)	$10,625	0.6%	$10,560	8.5%	$9,730	9.8%
Vasotec	705	(25.8)	950	(45.9)	1,790	(22.3)	2,305	(4.0)
Mevacor	150	(50.0)	300	(42.5)	520	(15.3)	600	(19.5)
Prinivil	900	(16.8)	1,250	14.4	1,075	31.9	815	18.1
Aggrastat	110	10.0	100	(23.1)	1 30	62.5	80	247.8
Anti-infectives	$1,070	(3.2%)	$1,105	(5.6%)	$1,170	(5.6%)	$1,280	(11.8%)
Crixivan	380	(12.6)	435	(17.9)	530	(20.3)	666	(1.5)
Primaxin	605	(5.2)	625	3.3	605	5.2	575	9.5
Cancidas	55	266.7	16	NM	0.0	NM	0.0	NM
Metabolic	$4,515	12.3%	$4,015	9.8%	$3,655	18.3%	$3,090	19.7%
Pepcid	400	(27.3)	550	(35.2)	850	(6.6)	910	(18.0)
Proscar	540	5.6	510	8.5	470	5.6	4 45	7.2
Propecia	225	4.7	215	10.3	195	5.4	185	122.9
Vaccines	$890	(4.3%)	$930	(1.6%)	$945	9.9%	$860	1.6%
Hepatitis vaccines	300	(6.3)	320	(7.2)	345	15.0	300	(4.8)
Viral vaccines	525	(2.8)	540	3.8	520	6.1	4 90	4.3
Other	65	(7.1)	70	(12.5)	80	14.3	70	15.5
Other Pharmaceuticals	$7,115	21.0%	$5,880	51.0%	$3,895	54.6%	$2,520	66.8%
Timoptic XL	200	(13.0)	230	(2.8)	255	(13.6)	295	(7.8)
Trusopt/Cosopt	440	5.0	415	13.7	365	10.6	330	24.5
Maxalt	275	17.0	235	23.7	190	81.0	105	288.9
Total Pharmaceuticals	$23,600	4.6%	$22,565	11.5%	$20,225	15.7%	$17,480	14.5%
Medco (a)	$31,650	20.8%	$26,200	30.1%	$20,140	32.2%	$15,235	31.5%
Total Product Revenue	$55,250	13.3%	$48,755	20.8%	$40,365	23.4%	$32,715	21.6%

(a) Medco sales of Merck products are reflected in individual product sales categories.

Sources: Merck & Co., CIBC World Markets estimates.

Exhibit 3

Merck & Co.: Selected New Product Pipeline

Drug	Therapeutic Category: Indication	Description	Stage of Development US	Stage of Development Europe
Invanz	Infectious disease: complicated infections	Carbapenem antibiotic	Filed	Filed
Vioxx (a)	Inflammation: rheumatoid arthritis	COX-2 inhibitor	Filed	Phase III
Fosamax (a)	Metabolic: male osteoporosis	Aminobisphosphonate	Approved	Filed
Vioxx (a)	Gastrointestinal: outcomes data (VIGOR)	COX-2 inhibitor	Approvable	Filed
Etoricoxib	Inflammation: osteoarthritis, RA, pain	COX-2 inhibitor	Phase III	Phase III
Singulair/Claritin (b)	Respiratory: asthma/allergies	Leukotriene antagonist/antihistamine	Phase III	***
Zocor/ezetimibe (b)	Cardiovascular: cholesterol lowering	Statin/cholesterol absorption inhibitor	Phase III	***
MK-869	CNS: chemotherapy-induced emesis	Substance P antagonist	Phase III	Phase III
Proscar (a)	Oncology: prevention of prostate cancer	5-alpha reductase inhibitor	Phase III	Phase III
Vioxx (a)	CNS: Alzheimer's disease	COX-2 inhibitor	Phase III	Phase III
KRP-297	Metabolic: diabetes	Thiazolidinedione	Phase II	Phase II
J-104132	Cardiovascular: congestive heart failure	Endothelin antagonist	Phase II	Phase II
Substance P	CNS: depression	Second generation substance P antagonist	Phase III	Phase III
HPV vaccine	Infectious disease: human papilloma infection	Vaccine	Phase II	Phase II
Rotavirus vaccine	Infectious disease: rotaviral infections	Vaccine	Phase II	Phase II
Invanz	Infectious disease: complicated infections	Carbapenem antibiotic	Filed	Filed

(a) Line extension/new indication.

(b) Co-development with Schering-Plough.

*** Not developed internationally.

Sources: Merck & Co., CIBC World Markets estimates.

Exhibit 4

Pharmaceutical Industry - EPS Estimates and Valuation

Company	Ticker Symbol	Rating	Price 06/21/01	52 Week High	52 Week Low	Annual Dividend	EPS 2000A	EPS 2001E	EPS 2002E	5 Yr % EPS Growth	P/E 2000A	P/E 2001E	P/E 2002E
American Home Products Corp (a)	AHP	B	57.09	65.25	50.37	$0.92	1.90	2.18	2.62	13	30.0	26.2	21.8
AstraZeneca PLC	AZN	H	48.29	52.37	42.20	0.46	1.64	1.76	1.76	8	29.4	27.5	27.5
Bristol-Myers Squibb Co (b)	BMY	SB	57.38	71.29	47.64	1.10	2.36	2.41	2.72	12	24.3	23.8	21.1
GlaxoSmithKline PLC (c)	GSK	H	64.15	66.62	47.16	1.17	1.86	2.05	2.30	10	29.3	26.4	23.6
Johnson & Johnson (d)	JNJ	B	64.30	67.60	40.25	0.72	1.71	1.87	2.18	12	31.8	29.0	24.9
Eli Lilly & Co	LLY	H	80.77	97.12	66.62	1.12	2.65	2.80	3.00	10	30.5	28.8	26.9
Merck & Co (e)	MRK	H	70.76	96.68	60.36	1.40	2.90	3.16	3.60	10	24.4	22.4	20.2
Pfizer Inc	PFE	H	40.64	48.06	34.10	0.44	1.02	1.30	1.67	17	39.8	31.3	25.9
Pharmacia Inc	PHA	H	44.16	64.00	40.00	0.54	1.45	1.75	1.94	13	30.5	25.2	22.8
Schering Plough Corp	SGP	H	36.55	60.00	33.86	0.64	1.64	1.67	1.86	10	23.6	23.1	20.8
Share Weighted Average						0.80				12.5	31.4	27.4	24.0
S & P Industrials (f)	SPII		1330.48	1862.09	1250.30	17.10	59.00	67.86	66.50		22.6	23.0	20.0
S & P 500 (f)	SPX		1167.56	1530.01	1081.24	16.67	68.12	60.67	57.60		21.0	22.9	20.1

Company	Ticker Symbol	Stock Price Performance (% Change) 1 Mo.	3 Mo.	12 Mo.	YTD	Div. Yield	Net Debt ($ Bill)	Market Value ($ Bill)	EV to 2000A Sales	EBITDA	Gross Profit	Relative P/E (SPX) 2000A	2001E	2002E
American Home Products Corp	AHP	(6.2)	2.7%	6.2%	(8.5%)	1.51	(0.532)	75.8	5.7	23.0	7.5	1.43	1.14	1.08
AstraZeneca PLC	AZN	(2.6)	10.4	7.1	(5.3)	0.96	(5.710)	86.2	5.0	21.1	7.0	1.40	1.20	1.37
Bristol-Myers Squibb Co	BMY	6.8	17.3	(21.7)	(19.7)	1.92	(1.887)	113.6	5.2	17.2	7.1	1.16	1.04	1.06
GlaxoSmithKline PLC	GSK	(7.2)	(6.9)	(12.0)	(3.1)	2.16	4.178	164.3	5.8	20.7	7.3	1.39	1.15	1.17
Johnson & Johnson	JNJ	18.9	12.4	4.0	6.6	1.33	(2.228)	168.9	5.7	25.7	8.2	1.51	1.27	1.24
Eli Lilly & Co	LLY	(2.3)	(25.6)	(20.0)	(11.7)	1.39	(1.800)	88.2	7.9	23.7	9.7	1.45	1.25	1.34
Merck & Co	MRK	(6.1)	(2.2)	(6.0)	(23.9)	1.98	2.665	165.3	4.2	17.9	9.4	1.16	0.98	1.01
Pfizer Inc	PFE	(5.8)	(9.5)	16.9	(11.9)	1.08	(1.451)	269.2	8.7	29.4	10.6	1.90	1.37	1.29
Pharmacia Inc	PHA	(21.6)	(23.6)	0.9	(25.4)	1.22	3.218	68.6	3.1	15.3	4.4	1.45	1.10	1.13
Schering Plough Corp	SGP	(18.4)	(30.9)	(30.9)	(28.9)	1.65	(1.294)	66.7	5.6	17.9	7.0	1.12	1.01	1.04
Share Weighted Average		(3.0%)	(4.2%)	(1.1%)	(10.9%)	1.49			6.2	22.9	8.4	1.49	1.20	1.19
S & P Industrials	SPII	(20.7)	(26.2)	(20.6)	(10.2)	1.29								
S & P 500	SPX	(17.5)	(22.0)	(16.0)	(9.8)	1.44								

(a) EPS figures are pro forma for the divestiture of agriculture. 2002 EPS includes $0.12 for a charge in accounting of goodwill. (b) EPS figures are pro forma for the divestitures of Clairol and Zimmer, including divestitures EPS estimates are $2.63 and $2.96. Pro forma EPS estimates for acquisition of Du Pont Pharmaceuticals and divestitures are $2.38 and $2.70, respectively. (c) EPS translated @ $1.62 for 2000 and $1.45 for 2001-02. (d) EPS figures are pro forma for the acquisition of ALZA, 2-for-1 stock split in effective 6/01. Excluding AZA, EPS estimates are $1.93 and $2.18. (e) The CIBC World Markets analyst(s) that covers this company also has a position in its securities. (f) First Call estimates.

Source: CIBC World Markets Corp. estimates, Company reports, Factset, ILX, First Call

The CIBC World Markets Corp. analyst(s) who covers Merck also has a position in its securities.

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8/22/2001

PFIZER INC. (PFE) "MKT. PERFORM"
PHARMACIA CORPORATION (PHA) "BUY"
MERCK & CO. INC. (MRK) "MKT. PERFORM"
JAMA ARTICLE FOCUSES ON THE POTENTIAL INCREASED CARDIO RISKS OF COX-2'S, FURTHER PENETRATION OF NSAIDs MARKET LIMITED

			52-Wk	Earnings Per Share				
Ticker	FY END	Price 08/21/2001	Price Range	2000	2001	2002	3-5 Yr Growth	Est. Chg?
PFE	12	40.64	48-34	1.02A	1.31	1.59	18%	N
PHA	12	44.16	64-40	1.45RA	1.74	2.04	12%	N
MRK	12	70.75	97-60	2.90A	3.15	3.45	11%	N

HIGHLIGHTS:

*POST HOC ANALYSIS SUGGESTIVE OF INCREASED CARDIO RISKS...An article published in the August 22/29, 2001, edition of the Journal of the American Medical Association (JAMA) seeks to define the risks of cardiovascular events associated with the COX-2 inhibitors, Merck's Vioxx, and PHA/PFE's Celebrex. An analysis of all available data "raises a cautionary flag about the risk of cardiovascular events with COX-2's, and mandates that a trial specifically assessing the cardiovascular risk and benefit of these drugs be conducted, particularly in light of their remarkable exposure, and popularity. The authors freely admit the limitations of their post-hoc analysis.

*CONSISTENT WITH FDA VIEWS OF A SIMILAR SIGNAL FOR BOTH DRUGS...Earlier this year, FDA held a meeting of their Arthritis Advisory Committee to discuss the outcomes of two outcomes studies, one VIGOR to show the reduced risk of GI complications versus NSAIDS, and second CLASS, to evaluate the same for Celebrex. These studies were filed to support a label change relative to NSAIDs, to either remove or temper the warnings of GI complications. At the meeting, both the committee and the advisory panel felt that there may be a signal of increased risk of cardiovascular events with BOTH drugs, but concluded that the studies were not prospectively defined to evaluate this, and that the study designs, and patient groups were significantly different in the two studies so the data could not be compared, and could not be used to draw any conclusions on cardio risks. However, the committee did feel that the data was strong enough to support the statement that patients at risk of cardiovascular events be given low-dose aspirin in addition to the COX-2. It was believed that the addition of aspirin might mitigate the GI benefits established.

*STILL NO ACTION ON APPROVABLE LETTERS...This summer, FDA issued approvable letters for Vioxx and Celebrex in response to the filing and review of the VIGOR and CLASS data. However, FDA has still not officially acted. We continue to believe, based upon the FDA review proceedings, which are consistent with the JAMA article, that the FDA will not distinguish between VIOXX and Celebrex, and may likely allow both companies to add the GI outcomes data to their labels, and also will expand the labels to include the potential for increased risk of cardiotoxicity, and recommend that all patients at risk, should also be given

low-dose aspirin. FDA will likely require both companies to do longer term studies to further define the cardiovascular risk profiles of VIOXX and Celebrex.

*SEQUENTIAL TRENDS FLATTENING...Recent trends for VIOXX and Celebrex show a flattening out in RX demand following a fever pitched uptake since their approval in early 1999. Quarterly sales in the U.S., for both Celebrex and Vioxx are in the $700 million area, and questions are already being raised about whether these drugs really do offer an improved risk profile, or whether they reduce the GI events, but raise the cardio risk. So, this is not new news, and is unlikely, therefore, in our opinion, to reduce sales. But rather, managed care's efforts to curtail the use of these drugs, by requiring that patients fail on one or two NSAIDs before they try a COX-2, largely due to their hefty relative price, will only get easier. Discussions such as the one raised in JAMA, the lack of a difference in the FDA's labeling of these drugs versus NSAIDs, and the recent guidelines issued in the UK by NICE (recommending their use as second line therapy after NSAIDs will serve to validate managed care's efforts.

WHAT ABOUT THE NEXT GENERATION OF COX-2'S?...PHA/PFE have filed for approval of valdecoxib, a clear upgrade from Celebrex due to once daily dosing, and apparent improved efficacy in pain. Merck's etoricoxib is expected to be filed at FDA by year end. FDA has already rejected PHA's parecoxib (injectable COX-2), and requested more data. will they do the same for the two oral follow-ons? Certainly, they may given the many questions raised, and the lack of clear answers.

EPS OUTLOOK REMAINS TENABLE FOR MRK AND PHA...Earnings estimates for both PHA and MRK have been coming down, and could continue to, depending on the trends for Celebrex, and Vioxx, as well as the FDA time line for valdecoxib and etoricoxib. These drugs are likely both company's most profitable, and have enjoyed blistering growth up until recently. Vioxx accounts for an estimated 11.6% of MRK's total human pharmaceutical sales, and Celebrex accounts for an estimated 22.8% of PHA's total pharmaceutical revenues. We continue to rate MRK a market perform, and view '02 forecasts as tenable, and certainly subject to downward revision. What is particularly troubling about MRK here, is the seem lack of concern, and even recognition that current and future EPS prospects are NOT competitive. PHA will get a $0.10 - $0.15 benefit from the recent changes in FASB accounting standards, which does provide some cushion, and we expect the company to move to divest its Ag business next year. We rate PHA a Buy. PFE will continue to put up the EPS numbers, and will grow at the industry's most impressive rate, but the pressures on the top line will likely continue to punish the multiple. We rate PFE a market perform.

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There is a (are) convertible issue(s) outstanding on Merck & Co. Inc. A member of the immediate family of an author of this comment has a long position in the shares of Merck & Co, Inc.
Ed White owns shares of Merck

09:44am EDT 22-Aug-01 Credit Suisse First Boston
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U.S. Major Pharmaceuticals: JAMA COX-2 Article
Possesses Limitations FBC

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U.S. Major Pharmaceuticals
JAMA COX-2 Study Possesses considerable limitations

Summary

An article in the current edition of the Journal of the American Medical Association (JAMA) recommends a cardiovascular study on the currently available COX-2 inhibitors (Merck's Vioxx and Pharmacia/Pfizer's Celebrex) as well as prescribing caution in patients at risk for cardiovascular events.

Pharmacia and Merck both issued rebuttals on Tuesday. Pharmacia reiterated that its CLASS (Celebrex) study found no increase in cardiac events and difficulties in statistically comparing heterogeneous patient groups as an inaccurate analysis methodology. Merck highlighted that prior FDA review of its Vioxx product line confirmed overall safety, with pending cardiovascular product labeling.

The JAMA researchers themselves point out several significant limitations in their study, including the use META statistical analysis methods across widely different clinical studies, heterogeneous patient populations in the study and the consideration that rheumatoid arthritis patients have a higher risk of heart attack.

From a financial standpoint, we believe the questions raised by the JAMA article will force both Merck and Pharmacia/Pfizer to reinforce safety messages to prescribing physicians. We note that our forecasts have already been adjusted for a relative slower rate of penetration by these drugs against traditional NSAIDs. Pharmacia (PHA, Buy, $44.16), Merck (MRK, Buy, $70.75) as well as Pfizer (PFE, Buy, $40.64), co-marketer of Celebrex, remain buy-rated stocks.

Executive Summary

JAMA Study Summary

The researchers in the JAMA article (Mukherjee, Nissen, Topol) performed an in-depth analysis of the two major COX-2 inhibitor trials, VIGOR (8076 patients) and CLASS (8059), a recent meta-analysis of four aspirin primary prevention trials as well as Adverse Events Reporting System reports in the U.S. The researchers then utilized a meta-analysis of the US Physicians' Health Study, the UK Doctors Study, the Thrombosis Prevention Trial, and the Hypertension Optimal Treatment trials with included 48,540 patients (25, 133 treated with aspirin and 23,407 on placebo) to compare the heart attack rate of these pooled studies against those seen in the VIGOR and CLASS trials.

-- FIRST CALL –

The annualized heart attack rate in the placebo group in the meta-analysis was 0.52%. The annualized heart attack rates for both the VIGOR and the CLASS trials were higher at 0.74% with Vioxx (rofecoxib) and 0.80% with Celebrex (celecoxib), prompting the conclusion for further study of cardiovascular risk.

We point out the following limitations in the JAMA study:

The researchers were generally more critical of the Merck VIGOR trial, in which Vioxx was shown to have a higher rate of cardiac events against the study control drug, naproxen. We note that the VIGOR trial did not include low-dose aspirin, and that the control drug (naproxen) is known to possess a cardio-protective, anti-platelet effect. This makes it extremely difficult to determine whether the difference as cardiac events seen in VIGOR results from a naproxen "benefit" or a Vioxx "liability."

The overall JAMA study relies on a META analysis design with many inherent limitations in making comparison across widely divergent patient groups.

Rheumatoid arthritis patients studied throughout the trial have an inherently higher rate of heart attack risk.

The JAMA article reiterates that the CLASS (Celebrex) study did not show a significant increase in cardiovascular event rates compared with NSAIDs, consistent with earlier conclusions. The researchers

suggest, but provide limited evidence, that this is tied to CLASS incorporation of low-dose aspirin and a less robust anti-platelet effects of diclofenac (Voltaren) and ibuprofen (Motrin/Advil) as study controls as accounting for this variance.

Recent FDA Deliberations: Confirm Overall Safety Profiling of Established COX-2 Agents

We note that an FDA advisory panel debated many of these same issues in February of this year in assessing relative labeling improvements for both Merck's Vioxx and Pharmacia/Pfizer's Celebrex. The advisory panel issued "approvable" letters to both companies on the basis of better gastrointestinal profiling versus selective NSAIDs, although highlighting some cardiovascular risk limitations for Merck's Vioxx. The higher cardiac event profile in Merck's VIGOR clinical trial was largely associated with the exclusion of aspirin use in the trial as well as the well-understood cardio-protective qualities of naproxen used as the comparative molecule in the trial. The CLASS and VIGOR trials were designed to assess gastrointestinal safety characteristics of respective Celebrex are still pending.

Conclusion

From a financial standpoint, we anticipate that the questions raised by the JAMA article will force both Merck and Pharmacia to continue to reinforce safety messages to prescribing physicians. We anticipate continuing to monitor on-going prescription trends for changes in physician behavior, although note that forecasts have already adjusted for a relative slower rate of penetration for the drugs against traditional NSAIDs.

Pharmacia and Merck as well as Pfizer (co-marketer of Celebrex) remain buy-rated stocks.

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--FIRST CALL--

Steve Scala/Ian Sanderson/Jonathan Moran

MERCK
(MRK: $67)

EPS (DEC) - DILUTED	2000	2001E	2002E
Q1	$0.63	$0.71A	$0.77
Q2	0.73	0.78A	0.84
Q3	0.78	0.84	0.94
Q4	0.75	0.82	0.90
Year	**$2.90**	**$3.15**	**$3.45**
P/E		21x	19x

Div: $1.40 Yld: 2.1% BV\Sh: $6.46

52-Wk Range: $60-97 Mkt. Cap: $153B

Average Daily Volume: 5.880MM Insiders Own <1%

Courtesy ILX
Table Omitted

New Products To Drive Uptick In 2002

UPGRADED TO BUY

We upgraded Merck to Buy from Neutral based on: (1) a growth rate poised for an uptick in 2002 vs. the depressed performance in 2001; (2) a handful of news events/triggers by year-end; (3) a pipeline likely substantially better than currently perceived; and (4) an attractive valuation. Our 12- to 18-month price target is $74, 21x 2002E EPS of $3.45.

- **New Products Temper Competitive Pressure On In-Line Drugs ...**

  New products, including **Vioxx** (arthritis/pain), **Singulair** (asthma), **Cozaar/Hyzaar** (cardiovascular), and **Fosamax** (osteoporosis), should offset some of the competitive pressures faced by older franchises. New product sales and Astra Merck revenue could total $16.5B in 2005, contributing $2.50 (56%) to projected EPS of $4.50.

- **. . . Driving Uptick In Growth In 2002**

  We estimate diluted EPS of $3.15 (+8%) in 2001 and $3.45 (+10%) in 2002, with the acceleration driven by new product strength, share repurchase, and infrastructure leverage. 2000-05 growth is forecast at 9%, below the 12-14% industry average. Patent/exclusivity expirations on Vasotec (expired 8/2000), Pepcid (4/2001), Mevacor (12/2001), Prinivil (6/2002), and Zocor (12/2005) are reflected in our estimates and assume pediatric extensions.

SPECULATION ON 2001-05 EPS OUTCOMES								
	2000	2001E	2002E	2003P	2004P	2005P	CGR	Comments
Other New Drugs	$0.70	$0.90	$1.05	$1.25	$1.40	$1.60	18%	- Cozaar, Singulair, Fosamax, AstraMerck
Vioxx/Etoricoxib	0.25	0.40	0.50	0.65	0.75	0.90	29%	- Coxibs; OA, pain, RA; Etoricoxib to be filed H2:01
Medco ex Merck	0.30	0.40	0.50	0.55	0.60	0.65	17%	- Fueled by penetration of existing accounts
Zocor/Mevacor	0.55	0.60	0.55	0.50	0.45	0.50	-2%	- New indications/Medco offsets competition
Joint Ventures	0.10	0.05	0.10	0.15	0.20	0.30	25%	- With JNJ, Pasteur Merieux, Aventis, Schering-Plough
Vasotec/Prinivil	0.30	0.20	0.10	0.05	0.05	0.05	-30%	- Pressure from competition/Vasotec patent expiration
Other	0.70	0.60	0.65	0.65	0.65	0.50	-7%	- Established drugs
EPS - DILUTED	$2.90	$3.15	$3.45	$3.80	$4.10	$4.50	%	Versus 12 HC industry average 2000-05
% Change	19%	8%	10%	10%	8%	10%	9%	
EPS - BASIC	$2.90	$3.20	$3.51	$3.86	$4.18	$4.59		
% Change	18%	8%	10%	10%	8%	10%	9%	

Source: SG Cowen

Current franchises and business leverage should support a low-double-digit total return through 2005, below that anticipated from the drug group overall. This factor, in tandem with modest pipeline visibility and few news events/triggers, suggests that the stock likely will perform in line with the group average.

CIBC World Markets *Equity Research*

September 25, 2001

Pharmaceuticals **Merck & Co.**

FDA Warning On Vioxx Sparks Sell-Off

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Investment Conclusion

- **FDA Gets Tough.** The FDA has issued a warning letter regarding improper promotion of Vioxx (arthritis, pain). Although warning letters for promotions are fairly common, the severity amid the heightened sensitivity to potential cardiovascular issues has taken the shares down almost 5% today.

- **Renewed Concerns.** The letter renews concerns of an added warning to the label, complicating market share expansion for COX-2s. Our view, dating back to the disclosure of VIGOR, is that the positive (lower GI bleeding) as well as the negative (potential cardiovascular risk) will both be incorporated into Vioxx' label.

- **FDA Toughens Stance.** The warning letter is indicative of the current FDA mindset (cautious) and increasingly aggressive policing of new drugs. However, implications about label changes are unclear, but not unlikely given the environment. This, however, appears reflected in MRK's valuation.

- **Stalled Share.** Vioxx and Celebrex (Pharmacia and Pfizer) are fighting each other and older drugs for share. Similar to VIGOR, Celebrex's CLASS trial was mixed (differed from VIGOR) and could prompt label revision as well. However, the obstacle is broader

managed care use, which we do not expect to alter near term.

- **Near Term Buying Opportunity.** Our HOLD rating on MRK is based on diminished financial flexibility amid low new product flow. The Vioxx/market share issue is likely weight upon the shares, MRK's valuation appears to reflect this. we are maintaining our Hold, but see opportunity for value-oriented investors below $65.

Outlook. Our Hold rating on MRK is based on the company's diminished financial flexibility in the wake of patent expirations, higher growth of the lower margin Medco business and resistance to market growth for MRK's COX-2 inhibitor, Vioxx. The largest issue, in our view, is Vioxx, which has enjoyed rapid growth since launch in 1999 (we expect sales of $3 billion this year). However, the class, which includes Vioxx and PHA/PFE's Celebrex, has stalled in terms of market share gains against older drugs (ibuprofen, naproxen, diclofenac), and that has been problematic. The FDA warning letter as well as a recent JAMA article raising concerns of cardiovascular risk will continue to pressure the stock, now trading close to its 52-week low. With the shares trading at just 16X our preliminary 2003 EPS estimate of $3.83, the shares appear to fully represent investor concerns. For investors with patience, the shares are compelling. However, without a product or strategic catalyst, we remain on the sidelines.

Rating:	**HOLD**
MRK-NYSE (09/25/01):	$61.06
52-week Range:	$60.35-96.68
Shares Outstanding:	2.3 Billion
Float:	2.3 Billion Shares
Market Capitalization:	$142 Billion
Dividend/Yield:	$1.40/2.0%
Fiscal Year Ends:	December
Book Value:	$6.33 per Share
FY 2001E ROE:	47.0%
LT Debt:	$7.4 Billion
Preferred:	Nil
Common Equity:	$14.9 Billion

Earnings per Share	
FY 2000	$2.90
FY2010E	$3.16
FY 2002E	$3.50

Earnings per Share	
FY 2000	24.4X
FY2010E	22.4X
FY 2002E	20.2X

Company Description

Leading drug company, with 2000 sales of $40 billion. Products include Cozaar and Zocor (cardiovascular), Fosamax (osteoporosis), Vioxx (arthritis) and Singular (asthma). Also owns Medco. PBM.

Quarterly EPS Estimates

		1 Qtr.	2 Qtr.	3 Qtr.	4 Qtr.	Year
FY 2000	Actual	$0.63	$0.73	$0.78	$0.75	$2.90
FY 2000E	Current	$0.71A	$0.78A	$0.86E	$0.80E	$3.16E
FY 2002 E	Current	—	--	---	---	$3.50E

Stock prices (as of 9/25/01) of companies mentioned in this report:

GlaxoSmithKline (GSK-NYSE $$52.24, Hold)
Pfizer (PFE-NYSE $36.67, Hold)
Pharmacia (PHA-NYSE $36.52, Hold)

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CREDIT SUISSE EQUITY RESEARCH	FIRST BOSTON	MERCK & CO. MRK

Merck Receives Warning Letter From FDA on Vioxx

Recommendation	BUY
Price (24 Sep 01)	63.99 (US$)
Target price (12 months)	80.00 (US$)
52 week high – low	94.88 – 61.00
Market cap (US$m)	146,501.20
Enterprise value (US$m)	146501.20
Regions / Country	**Americas / United States**
Sector	**Pharmaceuticals**
Date	**25 September 2001**

- On September 17, the Division of Drug Marketing Advertising and Communications in the FDA issued a warning letter citing Merck with making misleading statements in the promotion of the company's COX-2 inhibitor, Vioxx.

- The eight page letter, posted to the FDA website yesterday, took issue with Merck statements made in connection with Vioxx's cardiovascular safety profile as well as the risk related to concomitant use with the anti-clotting agent Coumadin (warfarin).

- The FDA is requesting that Merck provide a detailed response to all of the issues raised in the letter by October 1, including an action plan

including a complete cessation of certain promotional activities as well as issuance of a "Dear Doctor" letter related to Vioxx.

- Recent prescription trends have indicated that adverse publicity and cardiovascular concerns have contributed to erosion in Vioxx (as well as Celebrex) market share within the collective COX-2/NSAID market. We note that Merck is scheduled to sponsor an evidence-based clinical symposium at the upcoming World Congress of Nephrology meeting.

- We are projecting Vioxx revenues will increase 42% year over year to $3.06 billion for 2001, with growth moderating to the +14% level in 2002 to $3.49 billion. We maintain our Buy rating.

Merck is a global pharmaceutical company with significant franchises in cholesterol lowering/cardiovascular drugs, anti-ulcerants, anti-infectives, opthalmologic agents and vaccines.

Investment Summary

On September 17, the Division of Drug Marketing, Advertising and Communications in the FDA issued a warning letter citing Merck with making misleading statements in the promotion of the company's COX-2 Inhibitor, Vioxx. The eight page letter, posted to the FDA website yesterday, took issue with Merck statements made in connection with Vioxx's cardiovascular safety profile as well as the risk related to concomitant use with Coumadin, an anti-clotting drug generically known as warfarin.

The agency's charges specifically relate to statements made during Merck-sponsored audio conferences, in a company press release issued on May 22, and in statements made by sales representatives at two medical meetings.

The letter objects to Merck's assertion that the higher rate of myocardial infarction (MI) observed in Vioxx patients versus those on the comparator generic painkiller Naproxen in the VIGOR clinical trial was attributable to the fact that naproxen has a similar cardioprotective profile to aspirin. The FDA notes that while this hypothetical explanation is plausible, Merck's failure to disclose publicly the fact that it is hypothetical or back the statement with substantial evidence was unacceptable. The FDA warning letter further cites an alternative proposition that the increased rate of MI's observed in the Vioxx treatment group may be tied to possible Vioxx pro-thrombotic properties.

The FDA further accused Merck of engaging in promotional activities that minimize the potentially dangerous interaction of Vioxx with Coumadin. In particular, statements made during the company's audio conferences indicate that Vioxx can be used safely with Coumadin in post-operative treatment. Revised prescribing information for Vioxx disseminated in October 1999 states that bleeding events were reported, primarily in the elderly, in associate with increased in prothrombin time in patients receiving Vioxx concurrently with warfarin.

Further issue was take by the agency on Merck claims that Vioxx was proven safer than other NSAIDs as well as promotion of the drug in unapproved indications including rheumatoid arthritis, cancer prevention, gout and Alzheimer's disease.

The FDA is requesting that Merck provide a detailed response to all of the issues raised in the letter by October 1. The letter is expected to contain an action plan including a complete cessation of all false promotional activities as well as issuance of a "Dear Doctor" letter to correct misleading impressions created by the company's promotional and marketing efforts related to Vioxx.

COX-2 Inhibitor Weekly Prescription Trends

We have been closely following prescription trends in the COX-2 inhibitor/NSAID market, largely in the interest of evaluating potential volume and share erosion tied to recent adverse publicity published in the Journal of American Medical Association (JAMA) tied to potential cardiovascular safety concerns. For the week of September 14, Pharmacia's Celebrex new prescription market share in the collective COX-2/NSAID category fell to 17.6% from week ago levels of 18.0%. Vioxx (Merck's COX-2 inhibitor) new prescription market share also showed erosion, decreasing to 17.7% compared to 18.2% last week.

(Exhibit 1: COX-2 Inhibitor Market has been omitted.)

Upcoming World Congress of Nephrology Educational Symposium: "NSAIDS, Coxibs and Cardio-Renal Physiology: Clinical Implications

On Sunday October 14 at the San Fransisco Marriott, Merck is a primary sponsor of a symposium scheduled to run from 8:30 pm – 10:30 pm, coinciding with the World Congress o Nephrology meeting. The symposium, *NSAIDs, Coxibs and Cardio-Renal Physiology: Clinical Implications*, will evaluate a range of recent issues

recently captured in the press as well as medical journals over the past month. This symposium is expected to address the pharmacologic effects of NSAIDs and COX-2 inhibitors on cardio-renal physiology, under an evidence-based evaluation of the clinical implications of COX-1 and COX-2 inhibition.

Merck has retained a stance that Vioxx does not exhibit adverse cardiovascular signals, with conference symposium largely seeking to keep the debate on this issue based on scientific evidence grounds.

Vioxx Forecasts

During the second quarter earnings release, management reiterated comfort with the full year revenue guidance of $3.0 - $3.5 billion for Vioxx, although reiterating comfort at the lower end of this sales range for the year. We are projecting Vioxx revenues will increase 42% year over year to $3.06 billion for 2001, with growth moderating to the +14% level in 2002 to $3.49 billion.

We continue to monitor closely the relative growth trends in the U.S. markets for Vioxx, noting that continued adverse publicity trends or softening prescription bias will ultimately back into reductions in forward Vioxx sales trends.

We retain our Buy rating on Merck on defensive earnings growth attributes and low relative P/E valuation.

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Dain Rauscher Wessels
A DIVISION OF DAIN RAUSCHER WESSELS INCORPORATED

Merck & Co., Inc. (NYSE:MRK) September 25, 2001
Buy -Average; Price Target:$80
PHARMACEUTICALS

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FDA WARNS MERCK FOR VIOXX MARKETING PRACTICES

- The FDA has issued a warning letter to Merck that is critical of its marketing practices for Vioxx, claiming the company is minimizing possible cardiovascular safety risks.
- We do not believe this news will significantly alter current prescribing practices.
- We maintain our Buy-Average rating.

Price:	$63.99
52-Wk Range:	$96 - $60
Tr. 12 ROE:	51.2 %
3 Yr EPS Gr.:	9.0%
Shares Out:	2.35 billion
Book Value:	$6.29
Market Cap:	$150.12 billion

Fiscal Yr	Prev	EPS	P/E
Dec/2000A		$2.90	22.1x
Dec/2001E		$3.12	20.5x
Dec/2002E		$3.35	19.1x
2001 Q3		$0.83	

Merck & Co., Inc. has received a warning letter from the FDA, dated September 17, that criticizes its marketing practices for Vioxx--its coxib analgesic/anti-inflammatory agent. The company was cited for

minimizing the possibility of increased cardiovascular risk associated with the use of Vioxx relative to traditional non-steroidal anti-inflammatory agents such as Naproxen. The FDA has instructed Merck to cease the activities cited, discontinue using certain marketing materials, and to issue a "Dear Doctor" letter to healthcare providers who were/may have been exposed to the promotional activities in question.

We believe this development is unlikely to significantly alter physicians' prescribing practices, for several reasons:

- "Dear Doctor" letters are viewed by many as relatively ineffective in changing prescribing practices.
- It is likely that these issues are already common knowledge in the medical community, with any adjustments to the drug regimens of at-risk patients largely in place. In February, new clinical data for Vioxx was reviewed by an FDA advisory committee; and, while cardiovascular safety was an acknowledged concern and a significant topic of discussion, no labeling changes were recommended. In addition, a recent (August 22) article in the Journal of the American Medical Association described a re-analysis of existing clinical data, and concluded that further studies addressing cardiovascular safety are warranted. Finally, this issue was raised in a New York Times article in May.
- There is clinical data to suggest that Vioxx carries a reduced risk of severe ulcers and other gastrointestinal complications (which can be life threatening) compared to other available analgesics. We believe this potential benefit will likely outweigh

possible cardiovascular risks in many instances. Although data from the VIGOR clinical trial indicate that the relative incidence of heart attack was higher in Vioxx-treated patients relative to patients treated with Naproxen, the absolute incidence was relatively low--approximately four cases per 1,000 patients.

Stock Opinion:
We maintain our Buy-Average rating. MRK shares currently trade at an approximate 15% discount to those of the company's peer group, and at a slight discount to the S&P 500 as well. Our 12-month price target of $80 reflects an approximate 25% premium to the S&P 500 index applied to our 2001 EPS estimate. We view this premium as justified based on our assessment of the core, quality nature of this holding.

Company Description:
Merck & Co., Inc. is the second-largest U.S.-based pharmaceutical manufacturer and marketer with major strengths in the cardiovascular, endocrinology, anti-infectives, and vaccines segments. Its cardiovascular product lines collectively hold 40% and 25% of the worldwide statin and antihypertensive markets, respectively.

ADDITIONAL INFORMATION AVAILABLE UPON REQUEST

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Merck & Co., Inc. - Carl E. Byrnes (612) 373-1624												
	Q1 00A	Q2 00A	Q3 00A	Q4 00A	Q1 01A	Q2 01A	Q3 01E	Q4 01E	1999A	2000A	2001E	2002E
Total Sales	8,351	9,477	10,668	11,467	11,345	11,893	11,700	11,860	32,714	40,363	46,788	48,760
COGS	4,833	5,052	5,987	6,571	7,047	7,205	6,860	7,000	17,634	22,444	28,101	29,250
SG&A	1,417	1,524	1,452	1,774	1,506	1,637	1,625	1,650	5,200	6,168	6,419	6,625
R&D	523	548	610	662	647	602	666	700	2,068	2,344	2,505	2,650
Equity Income from Affiliates	(188)	(212)	(219)	(146)	(179)	(216)	(220)	(216)	(762)	(766)	(829)	(860)
Other (income)/Expense, net	71	87	96	96	56	70	40	60	64	349	216	200
Divest., acq. Business (gain)	-	-	-	-	-	-	-	-	-	-	-	-
Pre-tax Income	2,196	2,477	2,641	2,511	2,367	2,594	2,760	2,665	8,620	9,824	10,376	10,875
Tax Provision	694	766	806	747	710.2	778.1	828.0	799.5	2,729	3,002	3,116	3,263
Net Income	1,500	1,722	1,835	1,764	1,657	1,815	1,922	1,866	5,891	6,822	7,260	7,613
EPS-fd	$ 0.63	$ 0.73	$ 0.78	$ 0.75	$ 0.71	$ 0.78	$ 0.83	$ 0.81	$ 2.45	$ 2.90	$ 3.12	$ 3.35
Avg. Shares Outstd	2,365	2,346	2,343	2,356	2,346	2,328	2,320	2,305	2,405	2,352	2,325	2,275
Y/Y Trends	Q1 00A	Q2 00A	Q3 00A	Q4 00A	Q1 01A	Q2 01A	Q3 01E	Q4 01E	1999A	2000A	2001E	2002E
Total Sales	17.4%	18.2%	28.9%	27.9%	28.2%	25.5%	10.7%	3.3%	21.6%	23.4%	15.9%	4.2%
Operating Income	16.3%	18.8%	23.3%	17.0%	8.0%	4.1%	2.1%	1.5%	19.1%	18.9%	3.8%	4.7%
Pre-tax Income	19.1%	6.3%	18.2%	13.6%	7.9%	4.7%	4.1%	6.1%	6.0%	14.0%	5.6%	4.8%
Net Income	15.4%	16.5%	19.2%	12.2%	10.5%	5.4%	4.7%	5.7%	12.2%	15.8%	6.4%	4.9%
EPS	18.3%	19.9%	21.8%	13.7%	11.4%	6.2%	6.8%	8.1%	13.9%	18.4%	7.7%	7.1%
Ratio Analysis	Q1 00A	Q2 00A	Q3 00A	Q4 00A	Q1 01A	Q2 01A	Q3 01E	Q4 01E	1999A	2000A	2001E	2002E
Gross Profit Margin	45.4%	46.7%	43.9%	42.7%	37.9%	39.4%	41.4%	40.9%	46.1%	44.4%	39.9%	40.0%
SG&A Ratio	16.9%	16.1%	13.7%	15.5%	13.3%	13.8%	13.9%	13.9%	15.9%	15.3%	13.7%	13.6%
R&D Ratio	6.3%	5.8%	5.8%	5.8%	4.8%	5.1%	5.6%	5.9%	6.3%	5.8%	5.4%	5.4%
Operating Margin	23.5%	24.8%	23.8%	21.5%	19.8%	20.5%	22.0%	21.1%	24.2%	23.3%	20.9%	21.0%
Pre-tax Margin	24.8%	26.1%	25.0%	21.9%	20.9%	21.8%	23.5%	22.5%	26.3%	24.3%	22.2%	22.3%
Net Margin	16.9%	18.2%	17.4%	15.4%	14.6%	15.3%	16.4%	15.7%	18.0%	16.9%	15.5%	15.6%
Tax Rate	31.5%	30.5%	30.5%	29.7%	30.0%	30.0%	30.1%	30.0%	31.6%	30.6%	30.0%	30.0%
Major Compounds/Medco	Q1 00A	Q2 00A	Q3 00A	Q4 00A	Q1 01A	Q2 01A	Q3 01E	Q4 01E	1999A	2000A	2001E	2002E
Cozaar/Hyzaar	365	415	406	530	385	510	465	535	1,385	1,715	1,895	2,050
Vasotec/Vaseretic	470	530	460	330	260	295	235	275	2,305	1,790	1,065	800
Zocor	1,160	1,300	1,360	1,460	1,515	1,360	1,500	1,570	4,495	5,280	5,945	6,950
Fosamax	275	325	360	315	350	490	375	435	1,045	1,275	1,650	1,850
Vioxx	370	475	615	700	485	725	825	900	472	2,160	2,935	3,375
Singulair	170	210	235	245	300	375	275	325	500	860	1,275	1,425
Vaccines	130	255	175	220	240	245	225	235	860	912	965	975
Merck-Medco Sales	4,235	4,440	5,400	5,055	6,380	6,570	6,350	6,360	15,235	20,140	25,660	26,760

LEHMAN BROTHERS
EQUITY RESEARCH

September 25, 2001
Merck & Co (MRK - $63.99) 1 - Strong Buy
United States Healthcare
Major Pharmaceuticals
Company Update
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Sparked by DDMAC Over Vioxx Promotion

Investment conclusion

- The FDA released a warning letter on 09/17/01 that was posted on the FDA website this past Friday (09/21) that accused MRK of promotional activities related to Vioxx (rofecoxib) that were "false, lacking in fair balance, or otherwise misleading".

EPS (FY Dec)

	2000		2001			2002		% change	
	Actual	Old	New	St. Est.	Old	New	St. Est.	2001	2002
1Q	0.63	0.71A	0.71A	0.71A	-	-	-	-	-
2Q	0.73	0.78A	0.78A	0.78A	-	-	-	-	-
3Q	0.78	0.83E	0.83E	-	-	-	-	-	-
4Q	0.75	0.82E	0.82E	-	-	-	-	-	-
Year	$2.90	$3.14E	$3.14E	-	3.42E	3.42E	-	-	-
P/E	-	-	-	-	-	-	-	-	-

Summary

- Specifically, the Division of Drug Marketing, Advertising, and Communications (DDMAC) cited a total of six code violations in promotional audio conferences conducted by Merck employees.

- The violations pertained to the "misrepresentation" of the cardiovascular safety profile of Vioxx generated by the 8,000 patient VIGOR study. The general flavor of the violations related to MRK claims that Vioxx did NOT increase the risk of MI, rather naproxen was cardioprotective.

Market Data	
Market Cap	$156,48
Shares Outstanding(m)	2.29B
Float	2.27B
Dividend Yield	2.05%
Convertible	No
52 wk Range	96 – 60

Fiancial Summary	
Revenue FY01	$47.78
Five-Year EPS CAGR	11.1%
Return on Equity	50.03%
Current BVPS	6.46
Debt to Capital	0.6
Disclosure(s)	None

Stock Overview

Rating	Target
New: 1 – Strong Buy	New: 90.00
Old: 1 – Strong Buy	Old: 90.00

Summary (cont.)

- We do not believe this letter will be be predictive of the FDA's actions on the pending Vioxx label change. It remains our hypothesis that Vioxx will receive a positive label expansion highlighting the GI safety in RA. Further, we do not believe that a deleterious label will be forthcoming on safety with respect to thrombotic events.

The Letter

The DDMAC letter was addressed to CEO Gilmartin and signed by the director of the DDMAC, Thomas Abrams. Warning letters of this nature are certainly not unusual and in fact almost a staple of the pharmaceutical industry today.

> However, the fact that MRK is awaiting final approval for a label expansion for the GI safety of Vioxx makes the security of this letter and its possible implication on that label change very high.

The Violation

We do not debate the MRK may have violated several DDMAC codes. In fact, we are largely in agreement with the notion that the discrepancy in CV effects between naproxen and Vioxx are likely related to naproxen's ability to block platelet aggregation rather than Vioxx's propensity to promote platelet aggregation (we suggest that Vioxx is neutral). Ultimately, however, the absolute effect of Vioxx on CV safety is unknown. Hence, if MRK were to suggest otherwise, as the DDMAC has asserted, it certainly would be in violation of strict FDA regulations.

Potential Implications for Vioxx

While DDMAC may represent their interpretation of Merck's promotional activities of Vioxx, we understand that this division does not have any influence and remains independent of the FDA review process. Therefore the thought that this warning letter precedes a FDA decision to label Vioxx with warnings regarding cardiovascular events is incongruent. We should point out that we do not know how Merck will respond to the warning letter (a response will occur this week), yet Merck continues to believe that Vioxx does not increase cardiovascular events.

Merck also defends the vigor trial stating that Vioxx hit its primary endpoint of reducing GI events versus other commonly used pain medications (namely naproxen). The previous trial database and the currently available public database does not provide evidence of thrombotic events caused by Vioxx. In contrast, naproxen as a result of its effects on platelets may be cardioprotective. As noted in the current label, Vioxx is not cardioprotective. As pointed out in the FDA warning letter, DDMAC does not dispute Merck's claims.

We do not believe this warning letter will be predictive of the FDA's actions on the pending Vioxx label change. It remains our hypothesis that Vioxx will receive a positive label expansion highlighting the GI safety in rheumatoid arthritis. Further, we do not believe that a deleterious label will be forthcoming on safety with respect to thrombotic events. Clearly, patients at risk for thrombotic events will require cardioprotective medicines in addition to Vioxx.

Potential Implications for Merck

Merck is currently trading at 20 times this year's estimated earnings of $3.14 and 19 times next year's estimate of $3.42. Merck is not a growth stock, but given it is trading at a 20 percent discount to its historical average, it does represent value, in our view. Yesterday the stock was off 2.6 percent while its peers were up 0.8 percent. Curiously MRK was off less than 1 percent for the last 5 sessions while the S&P was off 14 percent and the DRG off 6 percent. Noise around the September 21 FDA warning letter, while the culprit of yesterday's activity, are aggressive.

While we do not know the timing of the FDA's moves on Vioxx, we remain optimistic on a positive outcome as illustrated above. Further as Prilosec is able to escape generic competition (patent expiry the first week in October), it remains our thought that Merck could be a beneficiary as current estimates do not include the 0.02-0.06 per quarter of upside. Most investors seem to remain somewhat pessimistic on the stock. We do not believe it can be overlooked. Our rating is 1-Strong Buy.

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Company Description

Merck, the third largest pharmaceutical company in the world, derives 60% of revenues from ethical pharmaceuticals, 34% from pharmacy management services, and 6% from animal health.

PHARMACEUTICALS **UBS WARBURG**

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Merck & Co **Rating: Buy**
(MRK-$63.99)[2]

Merck & Co.: FDA Warns Merck on Vioxx Marketing

Quarterly Earnings Per Share
(fiscal year ends December)

TABLE OMITTED

KEY POINTS

- **FDA issues warning to Merck for marketing only one side of the Vioxx safety argument.** On Friday, September 21st, the FDA issued a warning letter to Merck for aggressively promoting its side of the Vioxx safety debate. Merck was cited several times for promoting the story that the outcome of the VIGOR study was due to Naproxen being cardioprotective and that there is no unusual cardiovascular safety risk with Vioxx. The FDA pointed out that there is no definitive study proving or disproving either conclusion. Merck will not only

have to stop this activity, but also send out "Dear Doctor" letters clarifying the situation.

- **Vioxx cardiovascular safety debate continues.** Merck presented the results of its VIGOR study (comparing its new COX-2 arthritis drug Vioxx to Naproxen) to the FDA Advisory panel on February 8, 2001. The study results showed a statistically higher incidence of cardiovascular events with Vioxx than with Naproxen. Since then, there has been an on-going debate as to whether this result was due to Naproxen being "cardioprotective," therefore having below average risk, while Vioxx has average risk, OR that Naproxen has average risk for the class, while Vioxx has above average risk.

- **Merck may have no choice but to do another study.** The FDA's position appears similar to our own, which is that the data available to date are simply not definitive. We do believe that the only way to resolve this issue is to undertake a safety study with a true cardiovascular risk endpoint. Merck has never agreed to do this, but it may have no choice.

- **Safety concerns negatively impacting prescriptions.** The continued negative publicity has been hurting prescription trends for the COX-2 family (Merck's Vioxx and Pharamcia/Pfizer's Celebrex) for several weeks since the publication of a negative article in the August 22nd issue of JAMA (Journal of the American Medical Association). We had originally hoped that we would start to see weekly trends stabilize fairly quickly as the effects of the JAMA article faded. Unfortunately, if Merck

sends out a "Dear Doctor" letter, this downward trend is likely to continue for a few more weeks.

- **Merck has offsets to Vioxx slowdown, but clearly narrows the story and removes driver.** Outside of the Vioxx issue, Merck has some upsides that will now have to be used to offset a slowdown in Vioxx. Specifically, we are raising our Zocor revenue assumption for 2002 by $300 million to $7.2 billion, reflecting a benefit from the Baycol withdrawal. Also, we estimate Merck could get up to a $0.06 benefit in 2002 from the change in goodwill accounting. This essentially offsets our reduction in our 2002 Vioxx forecast from $3.55 billion to $3.25 billion (down $300 million). Therefore, we are leaving our EPS for 2001 and 2002 unchanged at $3.15 and $3.50, but clearly the quality is somewhat lower and the story is narrower. We still believe that with the stock trading at/below a market multiple, it offers good value and a favorable risk/reward. We continue to rate MRK Buy with a $87 price target.

- **Two other upsides not reflected in our model.** The dollar has weakened since Merck's profit warning earlier this year. Also, we have assumed Prilosec (anti-ulcer) goes generic in October 2001. The UBS analysts who cover AstraZeneca and Andrx believe legal issues could delay generic Prilosec into 1H02. Each quarter of delay is worth $0.03 - $0.05 to Merck.

Additional information available upon request

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Pharmaceutical Therapeutic Categories Outlook

The $355B worldwide pharmaceutical industry has terrific secular growth prospects, driven mostly by new products derived from rich R&D pipelines. New research tools for finding promising targets and strategies for reducing development time bolster the long-term outlook. These factors more than offset near-term uncertainties in the regulatory review process and debate on the need for prescription drug benefits. This comprehensive study forecasts trends in the major therapeutic drug categories through 2005. Each category is defined by therapeutic need, market size, growth outlook, major new compounds in development, and an assessment of individual company prospects. As shown below, the companies predicted to lead in "Market Share," "Total Therapeutic Positions," and "Leading Therapeutic Positions" are similar to last year. However, a new group of companies is poised for "Market Share Gain" through 2005. This analysis reaffirms our top picks in the group: **Bristol-Myers Squibb, Eli Lilly, Pfizer** and **Pharmacia.** We also like **Elan, Forest Labs** and **King Pharmaceuticals** in the mid-cap Rx segment.

WHICH COMPANIES WILL LEAD INDUSTRY THROUGH 2005?

Market Share	Market Share Gain	Total Therapeutic Positions	Leading Therapeutic Positions
GlaxoSmithKline	Eli Lily	Pfizer (12)	GlaxoSmithKline (4)
Pfizer	Novartis	Pharmacia (11)	American Home Products (3)
Merck	Amgen	GlaxoSmithKline (9)	Bristol-Myers Squibb (2)
Bristol-Myers Squibb	Johnson & Johnson	Johnson & Johnson (9)	Pfizer (2)
Aventis	American Home Products	Merck (9)	

SG COWEN PHARMACEUTICAL UNIVERSE

Company	Symbol	Stock Rating	9/27/01 Price	EPS 2001E	EPS 2002E	P/E 2001#	P/E 2002E
Abbott Laboratories	ABT	1	$50	$1.89	$2.25	26X	22X
American Home Products	AHP	2	57	2.18	2.60	26	22
Amgen	AMGN	2	57	1.18	1.35	48/	42
Bristol-Myers Squibb	BMY	1	53	2.39	2.60	22	20
Elan	ELN	2	48	1.90	2.30	25	21
Eli Lilly	LLY	1	79	2.80	2.85	28	28
Forest Labs	FRX	1	71	1.60	1.89	44	38
Genentech	DNA	2	42	0.75	0.95	56	44
GlaxoSmith Kline	GSK	2	53	2.11	2.40	25	22
Johnson & Johnson	JNJ	2	54	1.93	2.20	28	25
King Pharmaceuticals	KG	1	42	1.01	1.35	41	31
Merck	MRK	2	53	3.15	3.45	20	18
Pfizer	PFE	1	39	1.30	1.60	30.24	Pharmacia
Pharmacia	PHA	1	39	1.74	2.06	22	19
Schering-Plough	SGP	2	35	1.65	1.85	21	19

* * *

Arthritis

New Drugs Promise Greater Control of Widespread Disease

DEFINITION/BACKDROP

Arthritis encompasses numerous diseases that cause joint pain and inflammation, thus limiting movement of the joint and connective tissue. Arthritis is one of the most widespread chronic health problems: 18MM+ Americans suffer from arthritis and related diseases, and there are an estimated 35-50MM arthritis sufferers worldwide. nearly two-thirds of the arthritis patient population is women.

There are two prevalent forms of arthritis: Osteoarthritis (OA) and rheumatoid arthritis (RA). OA is a degenerative joint disease characterized by erosion of cartilage around bone joints; it primarily affects weight-bearing joints, such as the hip and knee. Nearly 16MM commonly older Americans and probably another 16-25MM people outside the U.S. have OA. RA is a more serious and disabling autoimmune disease in which connective tissue becomes inflamed. An estimated 2MM+ Americans, and perhaps 4-6MM people worldwide, have RA. RA is especially prevalent in younger women.

[Chart: Arthritis Category market Share by $ Sales has been omitted.]

Pharmacia/Pfizer and Merck dominated the arthritis/inflammation category in 2000, which market shares of 30% and 21%, respectively. In 2005, Pharmacia/Pfizer and Merck should continue to lead with 28% and 27% shares, respectively. Newer

rheumatoid arthritis drugs hold great potential, but may achieve lower sales at peak versus agents for osteoarthritis due to the smaller number of sufferers.

MAJOR TRENDS & ISSUES

- Coxibs, including Pharmacia's Celebrex (copromoted by Pfizer) and Merck's Vioxx, will dominate the osteoarthritis market through 2005, achieving sales of $12B+.

- "Second generation" coxibs offer little, if any clinical benefit over "first generation" products.

- New rheumatoid arthritis therapies have big potential given compelling efficacy and safety profiles, and could achieve sales of $5B+ in 2005. American Home Products/Immunex's Enbrel, Aventis' Arava, Schering-Plough/JNJ's Remicade, and Abbott/Cambridge Antibody Technology's D2E7 lead here.

- Our scatter plot shows that through 2005, Pharmacia/Pfizer and Merck should dominate this category, and this category is important to their growth. [Chart Arthritis/Inflammation: % Of Company 2000-05 Sales Growth From Category/2005 Sales Contributed by Company to Category ($ in B) has been omitted.]

ESTIMATED WORLDWIDE MARKET FOR ARTHRITIS DRUGS BY CLASS ($MM)

	2000		2005P		$ 00-05	NRx 87-00	
Drug Class	Market	%Total	Market	%Total	CGR	CGR	Comments
Coxibs	$4,794	45%	$12,100	54%	20%	NM	MRK's Vioxx/Etoricoxib, PHA/PFE's Celebrex/Valdecoxib, PHA's Parecoxib
TNF Inhibitors	948	9%	6,139	27%	45%	NM	IMNX/AHP's Enbrel, JNJ's Remicade, CAT/ABT's D2E7
NSAIDs	3,936	37%	3,067	14%	-5%	3%	NVS's Voltaren, AHP's Advil line dominate
DMARDs	189	2@	602	3%	26%	23%	AVE's Arava, AHP's methotrexate
Muscle Relaxants	252	2%	321	1%	4%	7%	TDCHF's Seltouch
Other Therapies	417	4%	297	1%	-7%	NA	Includes various anti-inflammatory products
Total Market	$10,546	100%	$22,526	100%	16%	7%	Driven by new Coxibs, DMARDs, and biologicals

Source: SG Cowen

DETAILED DISCUSSION

Selectivity Key for New Osteoarthritis Agents

Pharmacia/Pfizer's Celebrex and Merck's Vioxx, and their follow-on agents, will be the only selective coxibs marketed for a couple of years. Novartis, with COX/189, should be the third company to market post its H2:02 NDA filing. COX-2 is found in low amounts in most healthy tissues except the brain and kidney, but is expressed only when tissues are inflamed. COX-1 is widely expressed throughout the body, and it mediates production of prostaglandins that are essential in the gastrointestinal tract, kidney and platelets. Inhibition of COX-2 is believed to prompt anti-inflammatory, analgesic, and antipyretic effects, while inhibition of COX-1 can lead to stomach ulcerations and other prostaglandin-based side effects. Celebrex and Vioxx inhibit COX-2 with 100X+ greater in vitro potency than COX-1.

Celebrex/Valdecoxib: Should Maintain Roughly 50% Market Share

Pharmacia and co-marketing partner Pfizer have made Celebrex the market-leading franchise in terms of sales. We believe that the Celebrex/Valdecoxib franchise (coxibs for osteoarthritis, rheumatoid arthritis, pain) is positioned for dynamic growth through 2005, despite moderate downward revisions in our sales forecases and competition from Merck's Vioxx. There remains coxib market expansion potential for Celebrex and Vioxx, as 50%+ of arthritis pain patients still are on traditional NSAIDs. We believe that modest label improvements, resulting from the long-term safety data generated by the CLASS (Celebrex) and VIGOR (Vioxx) studies,

should support growth. Meanwhile, Celebrex has been launched in all major European markets, and data suggests that the product has outdistanced Vioxx. We forecase that Pfizer will continue to garner 30-40% of Celebrex/Valdecoxib sales as alliance revenue (assumed to escalate with sales growth) through 2005.

COMPARISON OF CELEBREX AND VIOXX

	Celebrex	Vioxx
Status/Indications	Marketed for OA, RA, FAP; more data needed for acute pain	Marketed for OA and asute pain; RA in phase III
Daili Dosage	200 mg once daily (OA); 200 mg twice daily (RA); 800 mg once daily (FAP)	12.5-25mg once daily (OA) 50mg once daily x 5 days (acute pain)
Effectiveness	Similar to NSAIDs	Similar to ibuprofen in OA and naproxen in acute pain
Half-Life	11 hours	17 hours
Safety Profile: Gastrointestinal	CLASS: missed primary (complications) endpoint; statistically significant for secondary (complications / symptomatic ulcers) endpoint	VIGOR: statistically significant for primary (clinical UGI) and secondary (complicated UGI) endpoints

COMPARISON OF CELEBREX AND VIOXX

	Celebrex	Vioxx
Edema	2.1% incidence of edema observed in clinical studies	Dose-dependent edema observed; 2.7% at 25 mg and 5.2% at 50 mg
Metabolism	Hepatic; cytochrome P450 2C9	Hepatic; cytosolic reduction (non-P450)
Drug Ineraction	Other drugs metabolized by cytochrome P450 2C9; fluconazole, lithium, furosemide, and ACE inhibitors; sulfa drug allergy	Methotrexate at 75mg (higher than 50mg RA dose); does not interact with drugs metabolized by cytrochrome P450 3A4 (numerous drugs)
Price	100 mg BID; $1.19 per tablet 200 mg qD or BID; $2.02 per tablet	12 mg and 25 mg qD: $2.02 per tablet

Sources: Company data, package inserts

Valdecoxib Should Sustain Growth of the Coxib Franchise

Valdecoxib, a second-generation coxib, is up to ten times more selective for the COX-2 enzyme than Celebrex, although the clinical relevance of this selectivity is unclear. Valdecoxib generated improvements in physical function in osteoarthritis patients that were on par with Naproxen 500 mg twice daily, but statistically significantly fewer gastroduodenal ulcers than Ibuprofen 800mg three times daily or Diclofenac 75mg twice daily. Valdecoxib's NDA was filed in February for osteoarthritis, rheumatoid arthritis, and acute pain. Our physician consultants believe that second generation coxibs offer no significant advance over the first-generation products, and only may provide a benefit in patients who do not respond to Celebrex and Vioxx. From the commercial standpoing, Pharmacia/Pfizer are well positioned given the acute pain indication and potential availability of an injectable formulation, which may encourage a switch of hospitalized patients from parecoxib to Valdecoxib.

COXIB MARKET POTENTIAL ($MM)

W.W. Antiarthritic Market	2000	2001E	2002E	2003P	2004P	2005P	'00-05 CAGR
Total Prescriptions	200,005	218,005	235,446	251,927	267,042	280,395	+7%
Current Price/Rx	$35.94	$35.94	$35.94	$35.94	$35.94	$35.94	
Market At Current Prices	$7,189	$7,836	$8,463	$9,055	$9,598	$10,078	+7%
Price/Rx At U.S. Branded Prices	$62.16	$62.16	$62.16	$62.16	$62.16	$62.16	
Market At U.S. Branded Prices	$12,432	$13,551	$14,635	$15,660	$16,599	$17,429	+7%
W.W. COXIB Buildup							
Conversion Prescription Rate	37%	45%	53%	61%	68%	76%	
Total COXIB Rxs	74,002	97,884	125,493	153,675	181,589	213,100	
Price/Rx	$65	$62	$60	$59	$57	$56	
Celebrex (PHA/PFE) Market Share	55%	50%	44%	39%	35%	31%	
Celebrex Sales	$2,634	$3,040	$3,310	$3,480	$3,600	$3,720	+7%
Valdecoxib (PHA/PFE) Market Share			7%	11%	14%	17%	
Valdecoxib Sales			$500	$1,000	$1,500	$2,000	NM
Vioxx (MRK) Market Share	45%	50%	46%	38%	34%	30%	
Vioxx Sales	$2,160	$3,000	$3,500	$3,400	$3,500	$3,600	+11%
Etoricoxib (MRK) Market Share			3%	11%	14%	17%	
Etoricoxib Sales			$250	$1,000	$1,500	$2,000	NM
COX189 (NVS) Market Share				1%	3%	4%	
COX189 Sales				$120	$300	$480	NM
Total COXIB Inhibitor Market	$4,794	$6,040	$7,560	$9,000	$10,400	$11,800	+20%

Source: IMS, SG Cowan

Assumptions:

- Current NSA ID price/day = $1.20; Branded NSAID price/day = $2.07; Coxib price/day = $2.40
- Price/Rx expected to decline due to lower prices internationally
- Total WW prescription data from IMS America and SG Cowen estimates.

❑ VIOXX SHOULD MAINTAIN ROUGHLY 50% MARKET SHARE

Vioxx (osteoarthritis and pain) currently holds 51.1% share in the Coxib market, and this share appears sustainable. Vioxx's success appears attributable to its label advantages (once daily dosing, pain claim) and Merck's widely respected marketing effort. The acute pain claim leads to a higher volume of short-use prescriptions. Post the FDA Advisory review of VIGOR (Vioxx) and CLASS (Celebrex) in early February, it appears that Vioxx's label may reflect superior language in terms of gastrointestinal safety than Celebrex. This may be offset by additional discussion of cardiovascular safety, although Celebrex's label also could be updated in this regard. In terms of global safety, physicians may view the drugs as similar. We believe these changes will confirm in physician's minds what already is known about coxibs. We believe our Vioxx and Celebrex sales estimates reflect the underlying growth trend in the arthritis market, a point that has generated concern among investors recently.

- **Etoricoxib Could Support The Franchise Further**

Etoricoxib targets indications in osteoarthritis, rheumatoid arthritis, and acute pain It has a different chemical structure and route of metabolism than Vioxx, and also is dosed once-daily. Etoricoxib is 106-fold more selective for COX-2 than Vioxx, and indeed is the most selective coxib in development. However, the importance of this selectivity is unknown. Similar to Vioxx, Etoricoxib is not a sulfonamide (Celebrex is a sulfonamide), and hence imparts no allergic reaction in sulfa-sensitive patients. Etoricoxib should not be associated with greater fluid retention than Vioxx, although this is not problematic for Vioxx at doses used clinically. An NDA filing is targeted for H2:01.

NEW PRESCRIPTION COMPARISON
1999-AUGUST 2001

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- **CLASS Suggested Superior Safety to NSAIDs, But...**

The CLASS study was a 6-12 month, double-blind study of 8,000 osteoarthritis and rheumatoid arthritis patients comparing Celebrex with older NSAIDs ibuprofen and diclofenac. In the study, Celebrex was dosed at 400mg twice daily (four times the normal osteoarthritis dose), while diclofenac was dosed at

75mg twice daily and ibuprofen was dosed at 800mg three times a day (standard doses). Patients on Celebrex experienced a lower incidence of ulcer, ulcer with complications, gastrointestinal blood loss, gastrointestinal symptoms, and renal and hepatic toxicities than patients on the other NSAIDs. There also was no significant increase in the incidence of myocardial infarction or cardiovascular disease in the Celebrex group. However, for the primary endpoint of upper gastrointestinal complications in all patients, the reduced rate of complications in the Celebrex arm had a p-value of 0.09, too high for statistical significance but a "miss" caused by only two complications. For the sub-segment of non-aspirin users, the lower rate of complications (0.4% versus 1.4% in the NSAIDs arm; p=0.04) is statistically significant. CLASS also achieved significance on the secondary endpoint of complications and symptomatic ulcers (p=0.03).

. . . VIGOR Achieved Statistical Significance

Pharmacia filed an sNDA for Celebrex with the FDA in June 2000 requesting labeling changes based on the CLASS study results. Merck also filed an sNDA for Vioxx based on its VIGOR study in June 2000. In April, the FDA issued approvable letters for Vioxx's VIGOR and Celebrex's CLASS data. VIGOR achieved statistical significance for the primary endpoint (clinical upper GI events - perforations, obstructions, bleeds, symptomatic ulcers; p=0.001) and secondary endpoint (complicated upper GI events - perforations, obstructions, major bleeds; p=0.005), but left lingering questions on cardiovascular safety. Then studies are difficult to

compare due to dosing and endpoint differences; in addition, patients in CLASS were able to use aspirin. The FDA Advisory committees reviewing CLASS and VIGOR clearly struggled with what conclusions should be drawn from these studies. Vioxx's label ultimately may reflect superior language in terms of gastrointestinal safety than Celebrex. This may be offset by enhanced discussion of cardiovascular safety, although Celebrex's label also could be enhanced in this regard. Hence, in terms of global safety, physicians may view the drugs as similar. The tables below depict the cardiovascular safety data from VIGOR and CLASS.

Cardiovascular Safety Profile of Vioxx from VIGOR Study

	Vioxx	Naproxen
All deaths	0.5%	0.4%
Cardiovascular Deaths	0.2%	0.2%
Myocardial Infarctions	0.5%	0.1%
Cerebrovascular Accidents	0.2%	0.2%

**Statistically significant*

Cardiovascular Events From CLASS Study*

	All patients	Non-Aspirin Users
Celebrex	0.5%	0.2%
Ibuprofen	0.5%	0.1%
Diclofenac	0.3%	0.1%

**Celebrex was not statistically different from either NSAID compared for the composite endpoint of cardiovascular events.*

- **JAMA Article Linked Cardiovascular Side Effects With Coxibs**

In August, an article in the *Journal of the American Medical Association* (JAMA) illustrated the possible link between the coxibs and an abnormally high rate of cardiovascular adverse events. NSAIDs inhibit both prostacylin (associated with platelet inhibition) and thromboxane (associated with platelet aggregation). The authors suggest that because the coxibs decrease prostacyclin, without impacting thromboxane, Celebrex and Vioxx may lead to increased thrombotic events. The article cited data from VIGOR, CLASS, and other studies in a meta analysis. No new data were discussed. The authors also state that the myocardial infaction rates for both Celebrex and Vioxx were significantly higher than placebo in a meta-analysis of patients in primary prevention trials. The authors conclude that "the available data raise a cautionary flag about the risk of cardiovascular events with coxibs. Further prospective trial evaluation may characterize and determine the magnitude of the risk."

- **. . . Differences in Cardiovascular Safety Profiles Possibly Due to Study Design**

While it is not possible to drawn definitive conclusions from the available data, differences in study design of VIGOR and CLASS could account for the varying results regarding cardiovascular safety. Patients in VIGOR did not receive low-dose aspirin, while 22% of patients received low-dose aspirin in CLASS. Also, the NSAID comparison in VIGOR was Naproxen, which Merck states is cardioprotective.

Given the negative publicity, we believe this issue is a near term negative for the coxib class, but longer term, it appear manageable, given that the benefits of these drugs likely outweigh the very small risk.

- **Issues Discussed During FDA Advisory Committees In February**

In February, the FDA Arthritis Advisory Committee discussed the approvability of the VIGOR and CLASS data for integration in the Vioxx and Celebrex labels. The panelists recommended approval of VIGOR and CLASS data, but issues surrounding cardiovascular safety of the coxibs were raised. The panelists questioned whether there was a low rate of cardiovascular events in the Naproxen group or high rate in the Vioxx group. The lower rate of cardiovascular events could have been due to Naproxen's cardioprotective effect, lack of cardioprotective effect from Vioxx, or both. Other questions the committee raised include: (1) does Vioxx increase cardiovascular events versus placebo, (2) can we neutralize negative cardiovascular effect by giving low-dose aspirin, without offsetting the GI safety benefit, and (3) what level of cardioprotection can be achieved by NSAIDs? The panelists noted that Celebrex is not a substitute for aspirin, possibly suggesting that class labeling could occur for the coxibs. The cardiovascular findings warrant consumer/provider awareness, and the panelists suggested that patients at high risk for a cardiac event should be given low-dose aspirin concomitantly with a coxib. The panelists believed that the overall safety of Vioxx was superior to Naproxen. The Committee believed that further studies were

necessary to definitely prove whether Vioxx, Celebrex or the coxib class in general are associated with a higher risk of cardiovascular events.

MorganStanley

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Price (October 18, 2001):
$69.05

Price Target:
$80

52-Week Range:
$96.63-60.40

October 22, 2001

Not All Sales Are Created Equal

- **3Q01 EPS of $0.84 in line with consensus and $0.02 above our estimate** MRK's operating margin of 22.8% was 150 basis points better than we expected. Though there were individual product variances, pharma sales were right in line with our forecast.
- **Vioxx sales were below our forecast, but Zocor was exceptionally strong** 3Q01 Vioxx sales were $795 mm vs. our forecast of $840 mm. However, Zocor exceeded our estimate by $115 mm, fueled by market-share gains from Baycol and a wholesaler buy-in.
- **MRK revised June 22 guidance on Vioxx, Zocor, and Singulair** Though Merck reiterated full-year EPS guidance of $3.12-3.18, 2001 Vioxx sales are now

expected to be in the $2.5-2.7 bn. range. However, ranges for Zocor and Singulair were raised.

- **The recent sell-off represents an overreaction, in our view** We are making no changes to our 2001 and 2002 EPS estimates of $3.13 and $3.42, respectively.

Price: Abs. and Rel. To Market & Industry

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Company Description

Merck is a global healthcare company specializing in research-based pharmaceutical products and pharmaceutical benefit services through its Merck-Medco unit.

FY ending Dec. 31:	2000A	2001E	2002E	2003E
EPS ($)	2.90	3.13	3.42	3.74
Prior EPS Ests. ($)	–	–	–	–
Consensus EPS Ests. ($)	–	–	–	–
CEPS ($)	3.44	3.73	4.08	–
P/E	23.8	22.1	20.2	18.5
P/E Rel. to (local Index)	–	–	–	–
P/CE	20.1	18.5	16.9	–
Price/Book	11.0	10.3	9.3	–
EV/EBITDA	–	–	–	–
Yield (%)	1.8	2.1	2.4	0.0

Market Cap ($ m)	158,086
Enterprise Value ($ m)	
Debt/Cap (03/01) (%)	
Return on Equity (03/01) (%)	0.5
L-T EPS Grth (%)	9.1
P/E to Growth	2.43
Shares Outstanding (m)	2,289.4

Q'trly EPS	2000A actual	2001E curr	2001E Prior	2002E curr	2002E prior
Q1	0.63	0.71A	–	NA	–
Q2	0.73	0.78A	–	NA	–
Q3	0.78	0.84A	0.82E	NA	–
Q4	0.75	0.80E	0.82E	NA	–

E = Morgan Stanley Research Estimate

Please see the important disclosures at the end of this report.

Not All Sales Are Created Equal

Summary and Investment Conclusion

MRK announced 3Q01 EPS of $0.84 (+6% year-over-year) -- in line with consensus and $0.02 ahead of our estimate. Though there were individual product variances in both directions, total pharmaceutical sales were exactly in line with expectations at $5,470 million, for growth of 6%. Vioxx sales fell short of our forecast despite the benefit of a $100 million wholesaler buy-in ($795 million versus our estimate of $840 million); however, we saw significant upside surprises with Zocor and Singulair. Zocor sales were an impressive $1.74 billion (+25%) versus our forecast of $1.59 billion and Singulair sales were $350 million vs. our forecast of $265 million. As anticipated, wholesaler buy-ins helped boost sales of several products, including Vioxx, Zocor, and Cozaar. Finally, Medco growth of 19% slightly outpaced our expectations of 18%.

On the spending side, the biggest variance was a better than expected gross margin (40.6% versus our estimate of 39.4%) -- likely attributable to the higher sales of Zocor than we'd been modeling. R&D spending was also about $50 million below our forecast, and management lowered its expectation for full year spending to $2.5 billion from $2.6 billion.

The stock has been weak as management again revised its June 22 guidance on several products (Vioxx, Zocor, and Singulair), though it reiterated full-year EPS guidance of $3.12-3.18. New guidance for Vioxx FY01 sales is $2.5-$2.7 billion versus June 22 guidance of $3.0-$3.5 billion. Though our published forecast of $2.95 billion reflected our doubts about the company's ability

to reach the earlier target, we are further lowering our forecast for the COX-2 inhibitor to $2.64 billion.

On the positive side, management significantly raised the range of expectations for the cholesterol-lowering drug, Zocor. Whereas previous guidance was for 2001 sales of $5.8-6.2 billion, management now feels comfortable that sales will reach the $6.5-$6.7 billion range. Zocor (like the other statins) has been a beneficiary of the August withdrawal from the market of Bayer's Baycol. Notably, however, a significant boost is also likely coming from the large Department of Defense contract, which includes Zocor at significantly discounted prices; as such, the increase in lower-margin sales of Zocor does not fully offset the reduction in Vioxx sales. The other positive swing is an increase in forecast Singulair sales for the year.

Management now expects sales in the range of $1.2-1.4 billion, versus previous guidance of $1.0-$1.2 billion.

We are maintaining our full-year 2001 EPS estimate of $3.13, despite 3Q results being $0.02 above our forecast. Since an estimated $200 million in sales were attributable to wholesaler buy-ins this quarter, we view the variance as largely a timing issue. We also remain comfortable with our 2002 EPS estimate of $3.42. We reiterate our Outperform rating on the stock and, quite frankly, were surprised at the magnitude of the stock's sell-off. Nothing that came out during the call or release has altered our outlook on the stock.

On our 2002 estimates, MRK shares now trade at a 14% discount to the group and a 2% discount to the broader market. At current levels, we believe the stock price already reflects significant bad news, and we see limited downside risk from here.

Near-term catalysts for the stock include the December 11 analyst meeting as well as the upcoming American College of Rheumatology conference, at which the COX-2 inhibitors are expected to have a meaningful presence. Our 12 month target of $80 assumes a relative P/E of just 1.03x that of the S&P, which gives little credit for any upside to MRK's pipeline, in our opinion.

What Went Well

Prospects for Zocor, Singulair, Cozaar. and Fosamax look better than our previous forecasts. Zocor: Sales of MRK's largest product beat our forecast by 7%, coming in at $1,740 million. vs. our forecast of $1,586 million. Though growth in demand has been consistently strong for Zocor, the product enjoyed incremental benefits this quarter from the withdrawal of Bayer's Baycol from the market as well as some anticipatory buying by wholesalers. Since August 3, Zocor has gained 2.2 market share points, or approximately 30% of the total share given up by Baycol. MRK estimates that the incremental contribution from Baycol sales in 3Q was $80 million. Zocor is now the exclusive statin on the Department of Defense formulary (whereas it previously shared the category with Baycol). Though these are clearly lower-margin sales, they remain profitable for the company. Zocor got a boost of another $80 million from speculative buying by wholesalers, due to their expectation of a 4Q price increase. Management believes this anticipatory buying is likely to continue next quarter, with normalization of inventory likely to occur in early 2002.

In addition to Zocor, three of MRK's other key growth drivers continued to deliver very solid growth. Cozaar/Hyzaar, MRK's angiotensin receptor blocker, showed growth of 33% to realize sales of $540 million.

We estimate approximately $55-60 million of these sales are from wholesaler stocking. Sales of Singulair for asthma were surprisingly strong at $350 million (vs. our forecast of $265 million) -- especially in light of the approximately $50 million wholesaler buy-in that the company had last quarter. Finally, Fosamax exceeded our forecast by about 7% and logged $450 million in sales this quarter. Growth is being driven by sales of the once-weekly formulation, which now makes up 75% of total scripts for the product. Like Singulair, Fosamax had a wholesaler buy-in of roughly $75 million last quarter, so we had anticipated a weaker showing this quarter. Both Singulair and Fosamax were recently launched in Japan, which played a role in the very strong international performance of both of these franchises.

Progress in the pipeline. After a relatively quiet period, MRK has had some positive news this quarter with regard to several pipeline products. The next generation COX-2 inhibitor, Arcoxia, has been submitted to the FDA and the ACR abstracts indicate the product has some unique features that may differentiate it from Vioxx and Celebrex (specifically, superiority data vs. Naproxen in RA). We also learned that the fixed dose combination of Zocor and ezetimibe has now moved into human studies (it had previously been in the formulation phase) and that Phase III studies in depression for the substance P antagonist are finally under way. (See additional detail in the Pipeline Update section.)

Still no generic competition to Prilosec. Though Prilosec sales are declining as AstraZeneca shifts its focus to its newest proton pump inhibitor Nexium, MRK continues to benefit from sales of the flagship product. The patent was scheduled to expire October 5, though

the FDA has not yet granted final approval of generics pending resolution of several patent issues.

Issues/Concerns

Controversy about Vioxx's cardiovascular safety is weighing on market share and growth. Vioxx sales fell short of our forecast despite the benefit of a $100 million wholesaler buy-in ($795 million vs. our estimate of $840 million). Because of the slower growth and the likelihood of a buy-out next quarter, we are lowering our 4Q01 sales forecast to $640 million, down 9% year over year. We have also significantly reduced our forecasts for next year to $3.05 billion from $3.6 billion. Vioxx has given up 240 basis points in New Rx market share since the August 9 article in the Journal of the American Medical Association (vs. a 100 bp decline in Celebrex). New Rx market share for the product now stands at 17.3% (below Celebrex share of 17.7%), reflecting both the declining share of the whole class as well as some degree of switching to Celebrex from Vioxx.

Wholesaler stocking boosted the quarter, creating a difficult comparison for 4Q01. Zocor enjoyed a contribution of approximately $80 million due to speculative buying in advance of an anticipated 4Q price increase. As the price increase has not yet taken place, management expects this trend to continue during the fourth quarter. Vioxx also got a boost from wholesaler buying this quarter, with an estimated $100 million impact this quarter due to a 4.9% price increase taken on August 31. Finally, we estimate about $55-60 million in wholesaler buying of Cozaar/Hyzaar, which also had a 4.9% price increase.

MRK's product mix is increasingly made up of highly discounted products. Because of the robust growth of Zocor and the fact that several of the company's

products are at the very end of their life cycle, MRK is paying out an increasing percentage of sales in the form of rebates/discounts. The company records these deductions as "other products," which is also the line on which AstraZeneca supply payments appear. We won't know the details of this line until the full therapeutic data are published in the 10Q (there are a few other small items that are included in this bucket); however, based on our estimate, "other products" were negative for the quarter. In other words, the amount of discounts/rebates actuallyexceeded the supply payments from AstraZeneca.

Pipeline Update

We expect MRK's December 11 analyst meeting to be upbeat, as the company has several new developments on the R&D side. Below are a few of the highlights: Zocor-Ezetimibe combination. MRK has completed the formulation phase and has begun preliminary studies with its fixed dose combination tablet of Zocor and ezetimibe, the cholesterol-absorption inhibitor it is developing through its joint venture with Schering-Plough (SGP). Ezetimibe monotherapy has been in Phase III and is expected to be filed with the FDA later this year or early next. We believe there is a good chance MRK can progress quickly through Phase III studies of the combination product and that the product could be on the market in 2003. (We think the better way to play the leverage potential for Zocor/ezetimibe, a product that will be positioned potentially to grab a sizable proportion of the existing $6.7 billion Zocor business, is through SGP, which stands to gain 50% of the profits).

Arcoxia (etoricoxib). MRK announced on October 11 that it has filed Arcoxia in the U.S. for the treatment of chronic and acute pain, rheumatoid arthritis, and

osteoarthritis. For competitive reasons, the company has not provided detail on the specific timeframe in which it has filed its NDA. It is certainly possible, however, that the product was filed somewhat earlier than the announcement. We note that one of the main abstracts to be presented at the upcoming ACR (American College of Rheumatology) demonstrates an efficacy and side-effect superiority to naproxen, the first time that a COX-2 has shown such an advantage over an older NSAID.

Vioxx. Labeling change in Europe. In the European Union, the Vioxx label was revised a couple of months ago. Though it's not appropriate to extrapolate the FDA's action, we were encouraged by the EU regulators' relatively benign treatment of the cardiovascular data. Specifically, the European label states that Vioxx is not a substitute for aspirin for cardiovascular prophylaxis because of its lack of effect on platelets.

Comparative trials versus Percocet. MRK has completed a head-to-head trial comparing Vioxx to Percocet, a DEA schedule II narcotic commonly prescribed for the treatment of pain. In a dental pain model, the study showed superiority of Vioxx over Percocet in pain relief over a six-hour duration. As the results of this study have now been publicized, the salesforce has begun actively detailing these findings, which further reinforce the product's profile as a potent pain reliever.

Incorporation of VIGOR data into the label. MRK received an approvable letter for its sNDA in April of this year, and is awaiting approval to include the data showing superiority over Naproxen with regard to gastrointestinal toxicity, i.e., perforations, ulcers and bleeds.

Substance Pantagonist. During the quarter, MRK began its Phase III trials in depression for the substance P antagonist.

Exhibit 1 (Excerpt)

Merck

Five-Year Estimated Sales and Earnings ($ millions)

	1999	2000	2001E	2002E	2003E	2004E	2005E	2006E
				• • • • •				
Vioxx (COX-2)	472.0	2,160	2,645	3,054	3,378	3,671	3,963	4,239
				• • • • •				

MERCK (MRK) CHARTS OMITTED

- Sales and Earnings Analysis: Third Quarter 2001
- Quarterly Income Statement Comparisons 1999-2006E
- Quarterly Margin Analysis 1999-2006E
- Quarterly Sales Model 1999-2006E

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04.50pm EST 22-Jan-02 Deutsche Banc Alex. Brown Inc. (B. Ryan/B. Cariello/E.) MRK: Despite Weak Vioxx Sales, MRK "Makes The Numbers"-Mkt. Perform -Part 1/2

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01/22/2002

MERCK & CO. INC. (MRK) "MKT. PERFORM"
Despite Weak Vioxx Sales, MRK "Makes The Numbers"
– Part 1/2

Date:	01/22/2002	EPS:	2000A	2001A	2002E
Price:	59.29	1Q	0.63	0.71	0.74
52 Wk Range:	86 – 57	2Q	0.73	0.78	0.73
Ann Dividend:	1.4	3Q	0.78	0.84	0.83
Ann Div Yld:	2.36%	4Q	0.75	0.81	0.85
Mkt Cap (mm):	136,426	FY(Dec.)	2.90	3.14A	3.15
3-Yr Growth:	11%	FY P/EPS	20.4X	18.9.X	18.8X
		CY EPS	2.90	3.14	3.15
Est. Changed No		CY P/EPS	20.4X	18.9X	18.8X

Industry: Pharmaceuticals/Major
Shares Outstanding (Mil.):2301.0
Return on Equity (2000): 43.0%

HIGHLIGHTS:

*4Q01 REVENUES AND EPS WERE IN LINE...rising 9.5% and 8%, respectively. Gross margins declined 360 basis points to 39.1% due to the mix shift towards the low margin Medco business. SG&A spending declined 12.3% to $1.56 billion, more than we forecasted, benefiting from an effort to lower costs, while R&D spending rose 8.2% to $716 million.

*KEY GROWTH DRIVERS YIELD MIXED RESULTS... Vioxx sales continue to disappoint, and were $95 mm below our forecast---falling 21.4% to $550 mm, as U.S. sales dropped 36% to $365 mm, with a buy-out of $125 mm. Zocor sales were up 41$ to $2.05B, with a $200 million buy-in, while Cozaar/Hyzaar sales were down 11.3% to $470 mm, and had a $60 mm buy-out. Both Fosamax and Singulair recorded solid sales of $470 mm (up 49%) and $350 mm (up 43%), respectively. Medco recorded a better than expected gain of 14.8%, to $6.96B, exceeding our forecast by $365 mm.

*MAINTAIN MARKET PERFORM RATING... Our EPS estimate for 2002 assumes flat EPS at $3.15, as we expect that this "transition" year will be characterized by onerous generic competition, and increased investment spending, following which, EPS should accelerate to double digits. We maintain our Market Perform rating, but expectations are low, and the shares appear attractive looking out over the longer term.

DETAILS:
8.0% EPS GROWTH ON 9.5% SALES INCREASE

MRK reported 4Q01 earnings of $0.81 per share, gaining $8% yr./yr. Total revenue of $12.6 billion was up 9.5% on a 14.8% gain at Medco and a 3.6% increase in the WW pharmaceutical business. WW pharmaceutical results benefited from volume growth of 8%, offset by a 2% pricing decline and a 2% negative hit from foreign exchange. In the all-important U.S. market, pharmaceutical sales were relatively flat with last year at $3.5 billion (2% volume growth offset by a 2% pricing decline).

The company's five key high-margin products provided mixed results, due in part to inventory buying patterns. Specifically, Vioxx posted WW sales of $550 million, down 21.4%, and was especially weak in the U.S., down 36% to $365 million, reflecting not only the slowdown of the coxib market in general, but also a $125 million buyout following a 4.9% increase in August '01, and $100 million buy-in in 3Q01. Zocor recorded strong WW sales of $2.05 billion, up 40.8% Cozaar/Hyzaar WW sales were $470 million, down 11.3%, Singulair had WW sales of $350 million, up 43%, and Fosamax WW sales were $470 million (up 49$. Zocor continues to benefit from the Baycol withdrawal, but also in the 4Q'01 from a substantial $200 million buy-in prior to the 10/31/01 price increase, while the decrease for Cozaar/Hyzaar reflects more intense competition as well as wholesaler buying that artificially boosted 3Q01 sales by an estimated $60 million. The combined sales of MRK's five growth products grew 20% during the quarter and accounted for 68% of total human pharmaceutical sales. Medco sales increased 14.8% to $6.96 billion.

MRK's gross margin came in at 39.1% vs. 42.7% in 4Q00, falling 360 basis points, due to the continuing unfavorable mix shift towards Medco, onerous currency exchange, negative mix in the AZN product line (i.e., the fixed rate of supply payments for the newer product, Nexium, are 27%--lower than the Prilosec rate of 32%, and ongoing margin pressure from products coming off patent. We expect this decline to continue over the next few quarters as these factors will remain negative, and forecast margins of 37.0% in 2002. We forecast stabilization in the low-37% range in 2003-2005.

R&D expenses of $716 million increased by 8.2% yr./yr., and as a percentage of sales were 5.7%, 10 basis points below 4Q00. Overall, R&D spending was up only 4.8% for the year, but we anticipate double digit increases in R&D spending over the next few years. Management guided R&D estimates for 2002 to the $2.9 billion area, an increase of 16%. Meanwhile, SG&A expenses declined 12.3% to $1.56 billion, down 310 basis points as a percent of sales yr./yr. to 12.4%, in an effort to cushion the blow of declining margins. SG&A expense for the year was up 0.9% to %6.22 billion, even with the addition of 1,000 new sales reps, due to the leveraging of technology, and the refining of the promotion and direct selling spending mix in an effort to maximize performance. In the first half of 2002, MRK intends to hire an additional 500 office based sales representatives. We project SG&A expense will rise 5.1% to $6.54 billion in 2002.

In 4Q01, MRK repurchased $300 million of its shares. For the year, the company repurchased $3.9 billion of stock, the largest amount spent on the share repurchase program in one year in the company's history. In 2000, the company approved a $10 billion share repurchase program, and there is a $3.7 billion remaining under that plan.

PHARMACEUTICAL PRODUCT DETAIL

VIOXX posted WW sales of $550 million in 4Q01, down 21.4%, with US sales of $365 million, off 36% yr./yr., and $105 million below our estimate, while international sales increased 42.3%, to $185 million. Vioxx now accounts for approximately 12% of MRK's WW pharmaceutical sales. The disappointing 4Q01 results can in part be explained

by a $125 million buy-out following a 4.9% increase and $100 million buy-in in 3Q01, but still compare poorly sequentially to 3Q01 revenues of $625 million in the U.S. Penetration of the analgesic arthritis market is stalled at about 40%, having suffered a setback due to the publicity surrounding potential cardiovascular risks and the resistance by managed care in allowing open access to the Cox-2 class in some plans. The major slowdown for Vioxx sales has had a major negative impact on the overall EPS outlook for Merck in 2002 and beyond. Our forecasts for Vioxx sales in 2002 and 2003 are now at $2.8 billion and $3.0 billion, respectively. In addition to the slowing coxib market in general, on November 19 Merck responded to the FDA's DDMAC warning by issuing two Dear Healthcare provider letters to 100 doctors and 2,000 pharmacists. Due to the major holiday disruptions of normal prescribing patterns, it is still too difficult to clearly discern the impact from this letter. However, overall it would appear that lately Merck is averaging about a 49.5% share of new prescriptions and 48% share of total prescriptions, lows that have not been seen in quite a while. While we cannot definitively link the Dear Doctor letters to the recent good performance of Vioxx weekly scripts, we will be closely monitoring the weekly data to see if a trend develops. What is clear however, is that overall script volumes have still not recovered to mid-2001 levels resulting from the damage of the JAMA publication in August of 2001 on the potential for increased cardiovascular risk with Vioxx therapy.

In December 2001, Vioxx was approved for acute pain and dysmenorrheal pain in 13 EU member states and in Norway and Iceland. Phase III clinical trials for Vioxx continue in the areas of chronic pain, colonic polyps and the treatment and prevention of Alzheimer's disease. In

April, MRK filed Vioxx for the treatment of rheumatoid arthritis with FDA, an indication that was granted late in 4Q01 in the member states of the EU. We are also waiting for a decision from the FDA on the proposed changes that both MRK and PHA have filed for, so that they can add the VIGOR and CLASS data to their respective labels. FDA may also require an addition to cardiovascular warnings, stating that COX-2s are not cardioprotective and that patients at risk of cardiovascular events should also be taking low-dose aspirin. Additional studies are necessary to fully characterize the cardiovascular issues, if there are any, for these drugs. While we do not expect any major changes in doctors prescribing habits, label changes may mean that managed care will have a tougher time limiting the penetration of these drugs in the arthritis market.

ARCOXIA (etoricoxib), MRK's second generation Cox-2 inhibitor, was submitted to the FDA in October 2001 for rheumatoid arthritis, osteoarthritis, acute pain and chronic pain. Most experts do not believe that the newer follow-on agents (PHA/PFE's Bextra and MRK's Arcoxia) will provide any additional incremental benefit in efficacy or safety. One 12-week study presented at ACR in November 2001 points to a greater pain efficacy of Arcoxia (90 mg daily) in the treatment of RA patients as compared to 1,000 mg of naproxen. This preliminary finding needs to be confirmed in larger studies, but is interesting in that most of the available data, including that for etoricoxib, indicate that the effectiveness of follow-on agents is very similar to that of older comparator NSAIDS.

ZOCOR WW sales in 4Q01 were ahead 41% to $2.05 billion, growing 55% in the U.S. to $1.5 billion. International sales of $550 million were ahead 13%. Sales in both the U.S. and Europe continue to benefit from the withdrawal of Baycol. In the U.S. there was a wholesaler buy-in of $80 million in 3Q01 in anticipation of a 4Q01 price increase. A more substantial $200 million buy-in ahead of the 5.9% on 12/31/01 contributed to the exceptional sales growth in the quarter. We believe that the cholesterol market will continue to grow in the high teens to 20% range as a consequence of the latest NCEP guidelines, which target a larger patient base and propose more aggressive treatment goals. Merck anticipates filing for new indications in 2002 based on the results of the Heart Protection Study (HPS), recently presented at the American Heart Association meeting in November. There are an estimated 24 million untreated U.S. patients that could benefit from statin treatment based upon their cholesterol levels. HPS potentially adds an additional 16 million patients, as it represents a new treatment paradigm---that treatment with Zocor is beneficial in patients with any 1 risk factor of coronary disease, regardless of their baseline cholesterol level. While Zocor's growth to date has been strong in the U.S. and the company added 1,000 sales reps this year, growth going forward should moderate due to increasing competition from more potent agents such as AZN's Crestor (launch anticipated in 2H02). Additionally, as the proportion of sales coming from discounted non-retail markets (e.g., Department of Defense, Veterans Administration) increases over time (currently 25% of US sales, growing 30%+), pricing will continue to be under pressure. Management's guidance for 2002 Zocor sales is $7.1 billion - $7.4 billion, and we expect sales to reach the high end of the range, and rise 10.2%, which

reflects substantial downward pressure on average selling prices. In 2003 and beyond, we expect sales growth.

Additional Information Available Upon Request

The following stock(s) is (are) optionable: Merck & Co. Inc. There is a (are) convertible issue(s) outstanding on Merck & Co. Inc. A member of the immediate family of an author of this comment has a long position in the shares of Merck & Co. Inc. Ed White owns shares of Merck.

SAMPLE SCIENTIFIC AND MEDICAL LITERATURE FROM 1991 THROUGH 2001

Ex. No.[1]	Date	Title	Publication	Excerpts
60	Dec. 1, 1991	Imbalance of Thromboxane/Prostacyclin Biosynthesis in Patients with Lupus Anticoagulant	Blood	An abnormal thromboxane/prostacyclin balance "may predispose affected patients to thrombosis." It has been theorized that inhibition of prostacyclin production "could play a role in the origin of thrombotic events."

[1] Exhibits referenced in this composite exhibit are attached to the Declaration of Robert H. Baron, dated August 12, 2005, in support of Defendants' Motion to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint.

Ex. No.[1]	Date	Title	Publication	Excerpts
61	Aug. 14, 1997	Altered pain perception and inflammatory response in mice lacking prostacyclin receptor	Nature	Mice that are prostacyclin receptor-deficient exhibited increased susceptibility to thrombosis, demonstrating that prostacyclin is an antithrombotic agent. "Endogenous prostacyclin has long been thought to be involved in the prevention of thrombosis..." "Our results establish that prostacyclin is an antithrombotic agent *in vivo*..."
62	Nov. 5, 1998	Platelet-Active Drugs: The Relationships Among Dose, Effectiveness, and Side Effects	Chest	"It is not established that interruption of PGI_2 [prostacyclin] formation is sufficient stimulus to initiate thrombosis." Recent studies with mice showed that prostacyclin was important in the prevention of thrombosis.

Ex. No.[1]	Date	Title	Publication	Excerpts
63	Jan. 5, 1999	Systemic biosynthesis of prostacyclin by cyclooxgenase (COX)-2: The human pharmacology of a selective inhibitor of COX-2	Proceedings of the National Academy of Sciences	A study of celecoxib showed that it suppressed prostacyclin as measured in urinary metabolites. "These data suggest that...COX-2 is a major source of systemic prostacyclin biosynthesis in healthy humans."
64	May 1, 1999	Effects of Specific Inhibition of Cyclooxygenase-2 on Sodium Balance, Hemodynamics and Vasoactive Eicosanoids	Journal of Pharmaco-logy & Experimental Therapeutics	The present implications of prostacyclin suppression are unclear, and "[i]t remains to be established whether treatment with specific Cox-2 inhibitors will suppress [the antithrombotic effects of prostacyclin production]." The biosynthesis of prostacyclin was mediated by COX-2, and prothrombotic stimuli induce COX-2 expression and prostacyclin generation.

Ex. No.[1]	Date	Title	Publication	Excerpts
65	June 17, 1999	Gastrointestinal Toxicity of Nonsteroidal Antiinflammatory Drugs	New England Journal of Medicine	There are questions regarding the selective COX-2 inhibitors, and speculation that "long-term therapy with these agents [COX-2 inhibitors] might increase the rate of thrombotic events in patients who were at increased risk for cardiovascular disease."

Ex. No.[1]	Date	Title	Publication	Excerpts
66	Apr. 1, 2000	Selective cyclo-oxygenase-2 inhibition with celecoxib elevates blood pressure and promotes leukocyte adherence	British Journal of Pharmaco-logy	"[T]wo recent reports highlighted the possibility that selective inhibition of COX-2 may, through inhibition of prostacyclin synthesis, promote thrombogenesis." "Based on the results of McAdam et al (1999) and Catella-Lawson et al (1999), one might speculate that inhibition of endothelial prostacyclin synthesis (COX-2), while sparing platelet thromboxane synthesis (COX-1) could lead to increased vascular tone and increased leukocyte and platelet aggregation." The authors concluded that studies of the potential adverse effects of selective COX-2 inhibitors in humans are warranted and that, until performed, caution should be exercised in suing these drugs in patients pre-disposed to thrombosis.

Ex. No.[1]	Date	Title	Publication	Excerpts
67	May 1, 2000	Rofecoxib, a Specific Inhibitor of Cyclooxygenase 2, with Clinical Efficacy Comparable with that of Diclofenac Sodium	Arthritis & Rheumatism	"[T]here has been a theoretical concern that specific inhibition of COX-2, which does not effect platelet function, may not protect the cardiovascular system to the same extent as NSAIDs," although this was not seen in this study.
68	June 26, 2000	A Randomized Trial of the Efficacy and Tolerability of COX-2 Inhibitor Rofecoxib vs Ibuprofen in Patients with Osteoarthritis	Archives of Internal Medicine	There are "a number of questions concerning the role of inhibiting COX-1 vs COX-2 in terms of the efficacy and safety of this widely prescribed class of drugs."

Ex. No.[1]	Date	Title	Publication	Excerpts
69	Aug. 2000	Thrombosis in Patients with Connective Tissue Diseases Treated with Specific Cyclooxygenase 2 Inhibitors	Arthritis and Rheumatism	COX-2 inhibitors "significantly reduce systemic production of prostacyclin. As a result, theoretical concerns have been raised that specific COX-2 inhibitors could shift the hemostatic balance toward a prothrombotic state." "These findings...are consistent with a hypothesis that thrombosis is an adverse consequence of inhibition of prostacyclin biosynthesis...Certainly these observations, together with the knowledge that COX-2 inhibitors selectively block prostacyclin biosynthesis, suggest the need for heightened surveillance of the consequences of specific COX-2 inhibition in patients with diseases that predispose to thrombosis."

Ex. No.[1]	Date	Title	Publication	Excerpts
70	Aug. 29, 2000	Cyclooxygenase-2 mediates the cardioprotective effects of the late phase of ischemic preconditioning in conscious rabbits	Proceedings of the National Academy of Sciences	"[T]he present investigation identifies COX-2 as a cardioprotective protein." The authors acknowledge that this conclusion "may appear to be in contrast with the extensive literature documenting a detrimental role of COX-2 activity in various pathophysiological conditions...We propose that the pathophysiological role of COX-2 is much more complex than heretofore appreciated, and that this enzyme may exert either beneficial or deleterious effects...From a practical standpoint, the recognition that COX-2 is an indispensable co-mediator of protection against ischemia/reperfusion injury during late PC has implications for the design and clinical use of COX-2 selective as well as nonselective COX inhibitors."

Ex. No.[1]	Date	Title	Publication	Excerpts
71	Sept. 2000	Selective Cox-2 inhibition in man—therapeutic breakthrough or cosmetic advance? (Editorial)	British Society for Rheumatology	"New insights into the biological functions of COX-2 should caution us from the uncritical use of COX-2 inhibitors..." "[L]ong-term safety can be established only with time and, as with all new types of drugs, we should be vigilant in recognizing possible new types of problems."

Ex. No.[1]	Date	Title	Publication	Excerpts
72	Nov. 1, 2000	Clinical Experience with Specific COX-2 Inhibitors in Arthritis	Current Pharmaceutical Design	"Since specific COX-2 inhibitors block production of systemic PGI_2, the question has been raised whether these agents may be prothrombotic. In fact, an imbalance of thromboxane/prostacyclin biosynthesis based on measurement of urinary metabolites has been previously proposed as crucial to the development of thromboses in patients with lupus anticoagulant." "Certainly these observations, together with knowledge that COX-2 inhibitors selectively block prostacyclin biosynthesis, suggest the need for heightened surveillance...in diseases that predispose to thrombosis."

Ex. No.[1]	Date	Title	Publication	Excerpts
73	Nov. 23, 2000	Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis (VIGOR study group)	New England Journal of Medicine	"Myocardial infarctions were less common in the naproxen group than in the rofecoxib group [in VIGOR] (0.1 percent vs. 0.4 percent)."

Ex. No.[1]	Date	Title	Publication	Excerpts
74	Dec. 1, 2000	Cyclo-oxygenase products and atherothrombosis	Annals of Medicine	"The widespread use of these drugs has increased interest in their role in the cardiovascular system." "[I]n individuals at risk for thrombosis for other reasons, depression of PGI_2 might be expected to increase their propensity to acute vascular occlusive events." It is "controversial" whether suppression of prostacyclin might "modulate the likelihood of acute vascular occlusive episodes in individuals with cardiovascular risk factors." "[T]he incidence of myocardial infarction [in VIGOR] was increased significantly, fourfold, in those receiving rofecoxib."

Ex. No.[1]	Date	Title	Publication	Excerpts
75	Jan. 8, 2001	Cyclooxygenase-2 Specific Inhibitors: Are They Safe?	American Journal of Medicine	"The advent of cyclooxygenase (COX)-1-sparing nonsteroidal anti-inflammatory drugs (NSAIDs) has once again focused clinicians, investigators, and patients on the issue of relative safety of NSAIDs in general and this new class of agents in particular." The theoretical risk of CV safety "has been investigated by looking at the occurrence of such events in a retrospective analysis of trials of rofecoxib." "Because of their COX-1-sparing effect, the COX-2 inhibitors do not affect platelet function and therefore cannot provide any of the cardioprotection that is based on this mechanism...[T]he fact that COX-2 inhibitors are capable of inhibiting prostacyclin while having no protective effect at the level of the platelet leads to the hypothesis that the use of these agents could be associated with an increased risk of thrombotic events."

Ex. No.[1]	Date	Title	Publication	Excerpts
76	Feb. 19, 2001	Cyclooxygenase Inhibition and Thrombogenicity	American Journal of Medicine	The clinical implications of selective versus nonselective inhibitors are unclear. "[I]n the Vigor study patients randomized to receive rofecoxib had a statistically significant increase in the incidence of major cardiovascular events, as compared with patients randomized to naproxen." COX-2 inhibitors "suppress prostacyclin formation without a concomitant inhibition of thromboxane biosynthesis." In elderly patients who are at highest risk for atherosclerotic disease, COX-2 specific inhibitors might promote platelet activation. "COX-2-specific inhibitors should be used with caution in patients with underlying prothrombotic states."

Ex. No.[1]	Date	Title	Publication	Excerpts
77	Apr. 21, 2001	NSAIDS and selective COX-2 inhibitors: competition between gastroprotection and cardioprotection	Lancet	"Two recent studies [VIGOR and CLASS]...have generated data on the trade-off between the cardiovascular and gastrointestinal effects of [COX-2 inhibitors and NSAIDs]." In VIGOR, "the incidence of myocardial infarctions was much higher in the rofecoxib group than in the naproxen group (although still very low in absolute terms: 0.4 *vs* 0.1%)." "Both trials clearly show that cardioprotection competes with gastroprotection."

Ex. No.[1]	Date	Title	Publication	Excerpts
78	Aug. 1, 2001	NSAIDs and COX-2 Inhibitors: Selective vs. Standard Use	Medical Crossfire	"Clinicians question...the widespread use of COX-2 inhibitors...citing an associated loss of cardioprotective effects." Cardioprotection is an issue of concern with COX-2 inhibitors. "The one thing we worried about with rofecoxib," noted one doctor, "is that it has no effect on the platelets. And the cardiovascular summary of rofecoxib that was accepted by the FDA is basically this: the risk of cardiovascular events with rofecoxib is similar to that with placebo or most NSAIDs, decreased cardiovascular effects with naproxen and with aspirin are due to their potent antiplatelet effects, and the cardiovascular results of rofecoxib are consistent with its COX-2 selectivity and lack of antiplatelet activity."

Ex. No.[1]	Date	Title	Publication	Excerpts
79	Aug. 1, 2001	Selective COX-2 Inhibitors as Risk Factors for Cardiovascular Events	American College of Rheumatology	"The August 22/29, 2001 issue of the Journal of the American Medical Association features a meta-analysis entitled 'Risk of cardiovascular events associated with selective COX-2 inhibitors' which has stirred considerable and immediate media attention and raises concerns about possible thromboembolic risks facing patients taking COX-2 inhibitors and physicians who prescribed them." "The decision to use selective COX-2 inhibitors is multidimensional, and must balance possible risks for major cardiovascular events against the benefits of these agents."

Ex. No.[1]	Date	Title	Publication	Excerpts
80	Aug. 9, 2001	The Coxibs, Selective Inhibitors of Cyclooxygenase-2	New England Journal of Medicine	"The difference in major cardiovascular events in the VIGOR trial may reflect the play of chance. The end point was prespecified, and the difference in the frequency of events was statistically small, but the absolute number of cardiovascular events was small (less than 70)." "Naproxen, the nonselective NSAID used in the VIGOR trial, may be protective against cardiovascular events."

Ex. No.[1]	Date	Title	Publication	Excerpts
81	Aug. 20, 2001	COX-2 inhibition and thrombotic tendency: a need for surveillance	Medical Journal of Australia	"In this article, we provide evidence that there is a potential for adverse occlusive vascular events associated with use of COX-2 inhibitors, and that doctors need to watch for this potential." "In the VIGOR study, there was a fourfold increase in the rate of myocardial infarction with use of COX-2 inhibitor, but in the CLASS study there was no effect on the rate...These results suggest that selective COX-2 inhibition may provoke thrombosis-related clinical events in patients already at risk and that low-dose aspirin or naproxen may be protective in this situation."
3	Aug. 22, 2001 - Aug. 29, 2001	Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors	Journal of the American Medical Association	"The availability of selective COX-2 inhibitors has raised several important clinical questions. These concern the prothrombotic potential of COX-2 inhibitors, differences in the antithrombotic effect of various NSAIDs, the mandatory use of aspirin with selective COX-2 inhibitors, and whether simultaneous use of aspirin negates the gastrointestinal protective

Ex. No.[1]	Date	Title	Publication	Excerpts
				effect of selective COX-2 inhibitors." "The increase in cardiovascular events in these trials was unexpected and evaluation of these end points was not prespecified. There remains considerable uncertainty in any post hoc analysis." "[D]efinitive evidence of [a prothrombotic] adverse effect will require a prospective randomized clinical trial." "Currently, no data exist on cardiovascular safety for the sporadic, intermittent use of these agents by individuals for musculoskeletal pain, which appears to be the most frequent pattern of use." "The available data raise a cautionary flag about the risk of cardiovascular events with COX-2 inhibitors." "Current data would suggest that use of selective COX-2 inhibitors might lead to increased cardiovascular events. Two smaller studies (Study 085 and Study 090) of rofecoxib that both allowed the use of low-dose aspirin did not demonstrate the significant

Ex. No.[1]	Date	Title	Publication	Excerpts
				increase in cardiovascular event rate noted in VIGOR." "The results of the VIGOR study can be explained by either a significant prothrombotic effect from rofecoxib or an antithrombotic effect from naproxen (or conceivably both)...Because of the evidence for an anti-platelet effect of naproxen, it is difficult to assess whether the difference in cardiovascular event rates in VIGOR was [sic] due to a benefit from naproxen or to a prothrombotic effect from rofecoxib."

Ex. No.[1]	Date	Title	Publication	Excerpts
82	Sept. 1, 2001	Reduced Risk of Acute Thromboembolic Events with Naproxen in Rheumatoid Arthritis Patients in the UK General Practice Research Database (GPRD) (Abstract)	Arthritis & Rheumatism (Supplement)	"RA patients currently treated with naproxen may have a reduced risk of acute major thromboembolic events..."
83	Sept. 1, 2001	The Relationship Between NSAIDs and Myocardial Infarction (abstract)	Arthritis & Rheumatism (Supplement)	"These findings do not support a relationship between the use of NSAIDs as a group and MI." However, the "[u]se of one specific NSAID, naproxen, did appear to be associated with a reduced rate of MI, but the mechanism of such an effect is not clear."

Ex. No.[1]	Date	Title	Publication	Excerpts
84	Nov. 1, 2001	Efficacy and safety of aspirin in the long-term management of atherothrombosis	Haemato-logica	"The cardiovascular safety of selective COX-2 inhibitors in arthritic patients at low cardiovascular risk is currently being debated." "At least three possible explanations can be entertained" to explain the VIGOR results: "a cardioprotective effect of naproxen," "a thrombogenic effect of coxibs," and "the play of chance."

Ex. No.[1]	Date	Title	Publication	Excerpts
85	Nov. 12, 2001	Cardiovascular Safety of Cox-2 Inhibitors	The Medical Letter on Drugs and Therapeutics	Increasing use of COX-2 inhibitors "has been accompanied by concerns that they may increase the risk of thrombotic cardiovascular events." "One recent review...compared annualized myocardial infarction (MI) rates in patients treated with COX-2 inhibitors in 4 studies (including Class and Vigor) to historical healthy controls not taking low-does aspirin and concluded that...rofecoxib increased risks for MI." "Until more prospective studies with and without low-dose aspirin are available, it would be premature to conclude that rofecoxib...increase[s] the risk of thrombotic cardiovascular disease."

Ex. No.[1]	Date	Title	Publication	Excerpts
86	Nov. 2001 – Dec. 2001	What have we learned from the large outcomes trials of COX-2 selective inhibitors? The rheumatologist's perspective	Clinical and Experimental Rheumatology	"The increased rate of cardiovascular thromboembolic adverse events among patients randomized to rofecoxib compared to those randomized to naproxen in the VIGOR trial is consistent with the lack of an anti-platelet effect for this COX-2 selective inhibitor." "Cardiovascular safety" is an "area of concern" in "the relative safety of COX-2 selective inhibitors" because these drugs inhibit prostacyclin but not thromboxane. "COX-2 selective inhibitors should not be used alone in patients at increased risk of serious cardiovascular thrombotic events, especially myocardial infarction...Either low-dose aspirin or another anti-platelet agent should be given in conjunction with the COX-2 selective inhibitor."

Ex. No.[1]	Date	Title	Publication	Excerpts
87	Nov. 2001 – Dec. 2001	Cox-2 inhibitors and the cardiovascular system	Clinical and Experimental Rheumatol-ogy	"We review the divergent incidence of cardiovascular events derived from the two large clinical trials of coxibs..." "If the difference in the cardiovascular event rates in VIGOR is a real one, two plausible hypotheses have been advanced in explanation. They are not mutually exclusive...[N]aproxen may be cardioprotective, just like aspirin" or COX-2 inhibitors suppress prostacyclin but not thromboxane.

SAMPLE PRESS ARTICLES IN 2000 AND 2001

Ex. No.[1]	Date	Title	Publication	Excerpts
March 27, 2000 – VIGOR Results Announced				
88	Apr. 12, 2000	Merck & Co., Inc.: Preliminary Results of Gastrointestinal Outcomes Study Presented	Biotech Week	"[S]ignificantly fewer thromboembolic events were observed in [VIGOR] patients taking naproxen in this GI outcomes study . . . As a result, Merck is notifying investigators, who are conducting other Merck studies with Vioxx or another investigational medicine in the same class, of protocol amendments to allow the addition of low-dose aspirin where appropriate."

[1] Exhibits referenced in this composite exhibit are attached to the Declaration of Robert H. Baron, dated August 12, 2005, in support of Defendants' Motion to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint.

Ex. No.[1]	Date	Title	Publication	Excerpts
89	Apr. 27, 2000	Merck's Vioxx Seen Facing FDA Scrutiny On Heart Attacks	Reuters News	"Vioxx . . . is likely to face stepped-up scrutiny from U.S. regulators because of the number of patients who suffered strokes and heart attacks after taking the medicine in new clinical trials, analysts said. 'The heart attacks and strokes could be a serious concern for the Food and Drug Administration, and could delay or derail Merck's plans to market Vioxx for rheumatoid arthritis,' said David Saks, manager of Gruntal & Co's Medical Sciences Fund." "Gruntal's Saks – who had previously forecast Vioxx could achieve annual sales of $2 billion by 2002, including between $200 million and $300 million for rheumatoid arthritis if it wins that approval – says FDA scrutiny could threaten those sales prospects. 'The rheumatoid arthritis indication would be icing on the cake. The larger question is how this issue (of heart attacks and strokes) might affect the whole cake,' he said, referring to the drug's total sales." "Swiss drugmaker Roche Holding Ltd is among the largest sellers of naproxen. . . 'To our knowledge, naproxen does not prevent heart attack or stroke,' Shelley Rosenstock, a U.S. spokesperson for Roche told Reuters. "ABN Amro's Corso said he was not reassured by Merck's suggestion that naproxen conferred protection against heart attacks and strokes. 'Medical authorities I've spoken to don't see any special reduction of such cardiovascular events in people taking naproxen,' Corso said."

Ex. No.[1]	Date	Title	Publication	Excerpts
90	Apr. 28, 2000	Merck's Vioxx Painkiller May Face Scrutiny at FDA, CNBC Says	Bloomberg News	"Merck & Co., the world's biggest drugmaker, may face safety questions from the U.S. Food and Drug Administration about one of its most important medicines, the painkiller Vioxx, CNBC reported." "The U.S. regulators may be concerned about the number of patients who took the drug during clinical studies and have suffered strokes or heart attacks, CNBC said, citing analysts."
91	Apr. 28, 2000	Merck Falls on Vioxx Concerns; Company Denies Risk	Bloomberg News	"Merck & Co. shares fell 2.8 percent after reports cited analyst concerns that the U.S. Food and Drug Administration might toughen its stance toward the painkiller Vioxx." "Investor worries stemmed from a study, first reported March 27, that found patients taking Vioxx had a higher incidence of stroke or heart attack than patients on a generic painkiller, naproxen. CNBC and Reuters said analysts thought the study could trigger regulatory scrutiny of Vioxx." "Investors and analysts have said they will be paying close attention as Merck presents the results of the Vigor study at a medical meeting in San Diego May 21-24."

Ex. No.[1]	Date	Title	Publication	Excerpts
92	Apr. 28, 2000	Merck Falls on Safety Concerns from Vioxx Arthritis Trial	Reuters News	"Shares of Merck & Co fell Friday amid Wall Street concerns about a study that cast some doubt about the safety of the company's blockbuster arthritis drug Vioxx compared with an older commonly used treatment for the disease." "The shares lost 3-1/2 to 68, or about 5 percent, in heavy afternoon trading on the New York Stock Exchange." "Analysts on Thursday told Reuters they were concerned about a Merck study of 8,000 rheumatoid arthritis patients in which patients taking Vioxx had more heart attacks than those taking a generic arthritis drug called naproxen." "[O]ther analysts have said they expect the U.S. Food and Drug Administration to give especially careful scrutiny to Merck's application to expand use of Vioxx to rheumatoid arthritis."

Ex. No.[1]	Date	Title	Publication	Excerpts
93	Apr. 28, 2000	Are the Feds coming after Merck?	Dow Jones Newswires	"Speculation ran rampant on Friday that the government regulators are pondering the safety of the drug giant's antiarthritis drug Vioxx. Merck shares staggered as much as 5.6% lower on the news." "Investors reacted to a Reuters report that Merck's hot-selling Vioxx may face intense scrutiny by the Food and Drug Administration." "[VIGOR] showed that patients using Vioxx had significantly more heart attacks and strokes than those on naproxen. What's not clear is whether Vioxx actually puts patients at higher risk of adverse events or whether naproxen confers heart-condition benefits." "If side effects were shown to occur at small dosages, Merck would have a 'huge problem' on its hands, he adds. For that reason, Smith downgraded the stock on Feb. 10 to Hold from Buy based on reduced enthusiasm for the drug." "With Vioxx's future tied to the Feds, Merck's stock is bound to suffer from more indigestion, says Saks."

Ex. No.[1]	Date	Title	Publication	Excerpts
94	May 1, 2000	Merck Shares Sink on Worries Over Vioxx	The Wall Street Journal	"Belated concern over the footnotes to preliminary results of an arthritis-drug experiment sent Merck & Co.'s shares down Friday in yet another indication that, in this volatile market, traders need little pretext to dump or buy shares." "Time and more data may sort out this argument. Then again, it may not. Since other anti-inflammatories may have effects on the heart, the best way to test the effect of Vioxx or Celebrex on the heart would be a comparison with a placebo. But since arthritis patients can't be allowed to suffer untreated, neither company's large experiments at this point include a placebo group." "Confused? That's what happens when researchers bicker."
95	May 21, 2000	Vioxx, Celebrex Aim to Profit from Improved Safety Labels	Reuters News	"Merck stirred controversy by disclosing that only one-fifth as many patients taking naproxen had heart attacks as those taking VIOXX." "Merck has offered only a credible theory why fewer patients taking naproxen had heart attacks than those taking Vioxx in the VIGOUR [sic] trial. 'But it's only a theory. There's nothing in the trial to prove the supposedly beneficial effects of naproxen,' Seiden said."

Ex. No.[1]	Date	Title	Publication	Excerpts
96	May 24, 2000	UPDATE 1 – Vioxx Shown Safer on GI Tract than Older Drug	Reuters News	"Data from the 8,000 patient study, called VIGOR, were presented in San Diego at Digestive Disease week, the nation's largest meeting of Gastrointestinal (GI) specialists." "[A]nalysts, including Brown Brothers Harriman's Mike Krensavage, said the heart-attack difference remained very much an issue, particularly given the demographics of the population taking Vioxx. 'The average age of patients in the study was 58, and 46 percent had some history of cardiovascular disease, so the targeted population is vulnerable to cardiovascular problems. Heart attacks are serious events. There's no way to say, 'This is nothing.' These data should encourage regulators to take a closer look at this drug,' Krensavage said."
97	Feb. 7, 2001	Merck's Vioxx Safety Warning Should Remain, FDA Review Says	Bloomberg News	"Agency reviewers pointed to an increase in risk of heart problems such as heart attacks in patients taking Vioxx compared to patients taking naproxen. Though Merck said the difference could be explained by beneficial effects of naproxen, and not harmful effects of Vioxx, the reviewers recommended data on the heart problems should be added to the drug's label."

Ex. No.[1]	Date	Title	Publication	Excerpts
February 8, 2001 – Arthritis Advisory Committee Hearing				
98	Feb. 8, 2001	Merck's Vioxx Unlikely to Cause Heart Problems, FDA Panel Finds	Bloomberg News	"The U.S. Food and Drug Administration advisory panel reviewed research showing patients taking Vioxx have higher rates of heart attacks than those taken naproxen, an older, cheaper painkiller. The difference could be the result of a cardiovascular benefit to taking naproxen, not a risk to taking Vioxx, the panel found."
99	Feb. 8, 2001	Merck Study Shows Vioxx Safer on Stomach - FDA Panel.	Reuters News	"The committee also expressed concern, however, that more Vioxx patients in Merck's trial suffered heart attacks and other cardiovascular events than patients taking naproxen. The panel recommended that the Vioxx label carry that information, even though members were not sure that Vioxx was responsible for the adverse effects."

Ex. No.[1]	Date	Title	Publication	Excerpts
100	Feb. 8, 2001	FDA Arthritis Advisory Committee Reviews Merck's Application for Revised Labeling for Vioxx(R) Based on Vioxx Gastro-intestinal Outcomes Study	PR Newswire	"Although the VIGOR study was a GI outcomes study and was not designed to show differences in cardiovascular effects, significantly fewer heart attacks were observed in patients taking naproxen . . . In extensive discussions, the Advisory Committee explored this finding, other studies of Vioxx and possible explanations for this result in VIGOR." "Other explanations were advanced by the FDA reviewer and were discussed with the Advisory Committee. The Committee recommended that the data on cardiovascular events in VIGOR be included in the labeling for Vioxx. In addition, the Committee agreed that the prescribing information for both Vioxx and Celebrex(R) (celecoxib) should reflect the fact that neither of these selective NSAIDs confer cardioprotective benefits and are not a substitute for low-dose aspirin."

Ex. No.[1]	Date	Title	Publication	Excerpts
101	Feb. 8, 2001	Merck Drug Should Note Heart Risk, Stomach Benefit, Panel Says	Bloomberg News	"The U.S. Food and Drug Administration advisory panel suggested that the Vioxx label highlight research showing patients taking the drug have higher rates of heart attacks than those taken naproxen, an older, cheaper painkiller." "Some studies suggest that naproxen may help keep the blood clear of clots, much like aspirin, thereby reducing the risk that a clot will cause a heart attack or a stroke, panelists said. Vioxx, designed to have no effect on clotting, would therefore appear to have a higher risk of heart problems when compared to naproxen."
102	Feb. 8, 2001	Scientists: Arthritis Painkiller Vioxx Causes Fewer Ulcers Than Naproxen	The Associated Press	"The panel said patients and doctors must be warned that in the study, Vioxx patients had twice the risk of heart attacks or other CV side effects as naproxen users. Why? No one's sure. Partly, naproxen may thin the blood, much like the aspirin used by heart patients to prevent blood clots, and thus using Vioxx instead deprived patients of the other drug's side benefit. However, some critics say Vioxx and Celebrex themselves may increase the risk of blood clots. FDA's advisers concluded more research is needed but that meanwhile, Vioxx's label should warn of the concern."

Ex. No.[1]	Date	Title	Publication	Excerpts
103	Feb. 8, 2001	UPDATE 3 – U.S. Panel Urges Label Changes for Merck's Vioxx	Reuters News	"The panel was concerned that more Vioxx patients in Merck's trial had heart attacks and other cardiovascular problems than patients taking naproxen. But members said it was possible that Vioxx did no harm and that naproxen protected the heart, as Merck argued."
104	Feb. 9, 2001	Federal Panel Suggests More Studies of Vioxx	The Star-Ledger	"[T]he panel reviewed data showing patients taking Vioxx had more heart attacks than those taking naproxen, an older and cheaper painkiller. But it was unclear if Vioxx caused a risk or if naproxen offers some type of cardiovascular benefit."

Ex. No.[1]	Date	Title	Publication	Excerpts
105	Feb. 9, 2001	Data: Vioxx Might Raise Heart Risk	USA Today	"Arthritis patients who take Vioxx because they think it's safer on the stomach should know that the blockbuster drug might increase their risk of suffering a heart attack, an FDA advisory committee concluded Thursday." "On the basis of that study, the advisory committee recommended that Merck be allowed to claim only that Vioxx is safer than naproxen in patients who are not also taking low-dose aspirin to protect against heart attacks." "Vigor also found that patients on Vioxx were more likely to suffer heart attacks and other cardiovascular complications than those on naproxen. The advisory committee recommended that this finding be noted on Vioxx's label."

Ex. No.[1]	Date	Title	Publication	Excerpts
106	May 22, 2001	Doubts Are Raised on the Safety of 2 Popular Arthritis Drugs	The New York Times	"Doctors are beginning to worry that Vioxx and Celebrex, two wildly popular arthritis drugs, may not be as safe as they were initially believed to be. Research presented to the Food and Drug Administration earlier this year showed that patients taking Vioxx, a Merck & Company drug, had a higher, but still relatively low, risk of heart attacks than patients taking an older pain reliever." "Wall Street is becoming aware of possible problems [associated with] . . . a large study sponsored by Merck last year [that] showed that patients taking Vioxx had four times the risk of heart attacks of patients taking another pain reliever, naproxen." "Richard R. Stover, a pharmaceutical industry analyst at Arnhold & S. Bleichroeder Inc., did his own analysis of what he called 'disturbing data' from Merck's study. In an interview, Mr. Stover said he was warning his clients, many of them institutional investors who hold Merck shares, that they should watch the issue carefully since it could hurt the company's stock price." "The current debate centers on whether the higher heart attack rate found in patients taking Vioxx is a result of the drug's actually causing damage in some patients or to an absence of the heart-protecting benefits that naproxen may have." "[Dr. Maria Lourdes Villalba] said that in her opinion, the potential safety advantage [of VIOXX] was offset by a higher risk of heart problems."

Ex. No.[1]	Date	Title	Publication	Excerpts
107	June 12, 2001	Personal Health; Newest Pain Killers Deserve A Closer Look	The New York Times	"Last month Wall Street got nervous about the safety of two of the hottest prescription drugs on the market, Celebrex and Vioxx, after a company-sponsored study suggested that they might increase susceptibility to heart attacks." "How would you interpret the findings of a study sponsored by Merck last year showing that patients taking Vioxx had risks of heart attacks four times as great as did patients taking naproxen? Would you conclude that Vioxx was risky or that naproxen had a protective effect not shared by Vioxx? Without a control group taking neither drug, telling whether Vioxx is hazardous or naproxen is beneficial is impossible." "Many doctors familiar with the biological activity of these drugs think the Merck study demonstrates what they have long suspected: that like aspirin and ibuprofen, naproxen protects against heart attacks. Better-designed studies are needed to tell who is right: Wall Street or these doctors."

Ex. No.[1]	Date	Title	Publication	Excerpts
108	June 18, 2001	Health Matters; When Hype Stands In for Solid Science	Los Angeles Times	"A trial involving Vioxx found that it was easier on the stomach than naproxen . . . But this study raised a new red flag. Patients taking Vioxx had four times the risk of heart attacks as patients taking naproxen. 'We're not sure whether Vioxx was associated with more heart attacks or naproxen was acting as aspirin to prevent heart attacks,' Wolfe says."
August 2001 – JAMA Article Published				
109	Aug. 21, 2001	Report Suggests Heart Link with Celebrex, Vioxx, but Critics Say More Research Needed	The Associated Press State and Local Wire	"The popular and heavily promoted arthritis drugs Vioxx and Celebrex have been linked by researchers to a small but troubling increase in the risk of heart attacks and strokes." "The researchers analyzed four studies that were not designed to examine the drugs' effects on the heart. Until such research is done, doctors should use caution in prescribing them to patients with heart disease, said Dr. Eric Topol, co-author of the analysis and chairman of cardiovascular medicine at the Cleveland Clinic." "The analysis, published in Wednesday's Journal of the American Medical Association, included a study that looked at the gastrointestinal side effects in 8,076 patients taking Vioxx or the pain reliever naproxen."

Ex. No.[1]	Date	Title	Publication	Excerpts
110	Aug. 21, 2001	Merck, Pharmacia Pain Drugs Tied to Heart Attacks, Study Finds	Bloomberg News	"Merck & Co.'s Vioxx and Pharmacia Corp.'s Celebrex, pain drugs taken by millions and generating more than $5 billion in annual sales, may cause blood clots and heart attacks, according to research in tomorrow's Journal of the American Medical Association."

Ex. No.[1]	Date	Title	Publication	Excerpts
111	Aug. 21, 2001	Study Sees Heart Attack Risk in Arthritis Drugs	Reuters News	"Celebrex and Vioxx, popular anti-arthritis drugs projected to ring up U.S. sales in excess of $6 billion this year, may carry a risk of blood clots leading to heart attack and stroke, according to a study published on Tuesday." "'[I]t is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents,' [the JAMA study] said." "[T]he drugs may also promote the formation of clots in blood vessels by decreasing production of a compound that promotes the widening of those vessels." "The study from the Cleveland Clinic appeared in this week's Journal of the American Medical Association and was based on an analysis of previous clinical trials. 'The available data raises a cautionary flag about the risk of cardiovascular events with (these drugs)... Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents,' it said."

Ex. No.[1]	Date	Title	Publication	Excerpts
112	Aug. 21, 2001	Vioxx, Celebrex Use Raises Cardiovascular Concerns-Study	Dow Jones News Service	"An analysis of clinical trials suggests a potential increase in the rate of heart attack, stroke and other cardiovascular events among patients treated with Vioxx from Merck & Co. Inc. (MRK) and Celebrex from Pharmacia Corp. (PHA) and Pfizer Inc. (PFE), according to an article in the Aug. 22-29 issue of The Journal of the American Medical Association." "'[T]hese concerns [about the blood-clotting tendencies of COX-2 inhibitors] must be addressed in dedicated trials,' Topol [senior author of the JAMA article] said. 'It could turn out that the COX-2s are very helpful but what we have so far indicates a higher heart attack rate.'" "According to the Cleveland Clinic research, which considered the various trial results of 48,450 patients, those patients given a placebo had a heart attack rate per year of .50%, while the rate with Vioxx was 0.74% and Celebrex was .80%."

Ex. No.[1]	Date	Title	Publication	Excerpts
113	Aug. 22, 2001	2 Drugs Linked to Increased Heart Risk	The New York Times	"Researchers have linked chronic use of the popular and heavily promoted new anti-inflammatory drugs Vioxx and Celebrex to a small but troubling rise in the risk of heart attacks and strokes." "The analysis is to be published today in the Journal of the American Medical Association."

Ex. No.[1]	Date	Title	Publication	Excerpts
114	Aug. 22, 2001	Note of Caution: Study Raises Specter of Cardiovascular Risk for Hot Arthritis Pills – Vioxx and Celebrex Marketers Dispute the Research – A Spurned Appeal to JAMA	The Wall Street Journal	"[N]ew research raises the possibility that the breakthrough drugs could have a worse side effect: an increased risk of heart attack." "The cardiac concerns appear in an analysis by the noted cardiologists Eric J. Topol and Steven E. Nissen, chairman and vice chairman, respectively, of cardiovascular medicine at the Cleveland Clinic. Their study of Vioxx and Celebrex concludes, 'Current data would suggest that the use of these so-called 'COX-2 inhibitors' might lead to increased cardiovascular events.'" "Their conclusions, published in today's Journal of the American Medical Association, are generally more critical of Merck's Vioxx [than of Celebrex]. The authors say patients taking Vioxx had more than twice as many heart attacks, strokes and other cardiovascular events as patients getting an older, generic arthritis drug, naproxen."

Ex. No.[1]	Date	Title	Publication	Excerpts
115	Aug. 22, 2001	Heart Risk from Celebrex, Vioxx?: 'Super Aspirin' Makers Contest Analysis	The Washington Post	"The popular painkillers Celebrex and Vioxx may slightly increase a person's risk of having a heart attack, according to an analysis of clinical studies of the 'super aspirin' drug." "'It's a cautionary flag that seems to say that something is going on that needs further exploration,' said Eric J. Topol, a cardiologist at the Cleveland Clinic and one of the authors of the analysis, which appears in the Journal of the American Medical Association." "In one trial, about 8,000 people with rheumatoid arthritis were randomly assigned to get either Vioxx or naproxen, an NSAID. There were more than twice as many cardiovascular events in the Vioxx group as in the naproxen group – 46 vs. 20."

Ex. No.[1]	Date	Title	Publication	Excerpts
116	Aug. 22, 2001	Heart Attack Link to Arthritis Drugs	Financial Times (FT.com)	"Merck, Pharmacia and Pfizer will on Wednesday be put on the defensive over independent scientific evidence that their billion-dollar arthritis drugs could be linked to an increase in heart attacks." "The companies involved have been campaigning to have better warning labels on the drugs approved by the US Food and Drug Administration. However, an analysis of clinical trials by scientists from the Cleveland Clinic Foundation suggests that there is a potential increase in the rate of heart attacks, strokes and other cardiovascular events among patients on the drugs."

Ex. No.[1]	Date	Title	Publication	Excerpts
117	Aug. 22, 2001	UPDATE 1 – Anti-Arthritis Drugmakers Take Hit after Study	Reuters News	"Shares of Merck & Co Inc. and Pharmacia Corp. are expected to remain under pressure after a roller coaster trading day on Wednesday set off by a study questioning the safety of their popular anti-arthritis medicines Vioxx and Celebrex." "The study by top cardiovascular researcher Eric Topol, who chairs the Department of Cardiovascular Medicine at the Cleveland Clinic, said that the medicines may carry a risk of blood clots leading to heart attack and stroke." "Wall Street analysts said the study will fuel debate over the two drugs, threatening already slowing sales." "Richard Evans of Sanford Bernstein, says 'with a study like this coming from someone like Topol, the debate becomes more apparent to physicians and consumers. . . I think the average physician will be more circumspect about writing prescription for these drugs, and your average consumer will be less likely to ask for the drug from their doctor." "The [Cleveland Clinic] study said the drugs may also promote the formation of clots in blood vessels by decreasing production of a compound that promotes the widening of those vessels."

Ex. No.[1]	Date	Title	Publication	Excerpts
118	Aug. 22, 2001	Study Finds Health Risks in Popular Arthritis Medicines Vioxx, Celebrex	Los Angeles Times	"Two of the most widely used new drugs for arthritis may increase a patient's risk of heart attack and stroke and probably should not be used by people who already are at high risk for cardiovascular problems, researchers from the Cleveland Clinic report today." "[T]he study reported in today's issue of the Journal of the American Medical Assn. offers a cautionary note on their use. The report reviewed previous studies of the two drugs and suggests that they can increase formation of blood clots, leading to heart attacks and other cardiovascular problems." "Topol himself takes the drugs because of an arthritic knee. They are 'a great class of medicines,' he said. 'But if I had risk factors for heart disease, I would be more concerned right now. I would take aspirin or switch drugs until we have more concrete evidence.'" "'We would not agree that there is no cardiovascular risk,' said Dr. Lawrence Goldkind, acting deputy director of the FDA's division of anti-inflammatory, analgesic and ophthalmic drugs. Nor would the agency say there is a risk. 'We will continue to evaluate the information as more becomes available,' he added."

Ex. No.[1]	Date	Title	Publication	Excerpts
				"[The VIGOR] study left unclear whether Vioxx caused an increase in heart attacks or whether the naproxen prevented them, Topol said." "To determine whether they were observing a higher risk caused by Vioxx and Celebrex or simply a lowered risk caused by aspirin and naproxen, the Cleveland Clinic group compared the Vioxx and Celebrex users to a group of patients receiving a placebo in a large study that compared aspirin to a placebo. Using that control group, they concluded that the Cox-2 inhibitors doubled the risk of heart attacks."
119	Aug. 22, 2001	Two Arthritis Drugs Could Heighten Risk for Heart Patients	The Plain Dealer	"[Cleveland Clinic researchers] concluded that people who took Vioxx or Celebrex in two of the studies stood a 50 to 60 percent greater chance of having a heart attack or stroke than people in two other studies who took only sugar pills." "Heart safety is an important issue for the drugs' main users: the elderly and people with rheumatoid arthritis. Both groups are at increased risk of cardiovascular disease."

Ex. No.[1]	Date	Title	Publication	Excerpts
120	Aug. 22, 2001	'Super Aspirin' Alarm Sounded	St. Petersburg Times	"The popular painkillers Celebrex and Vioxx may slightly increase a person's risk of having a heart attack, according to a new analysis of clinical studies of the 'super aspirin' drugs." "The researchers analyzed four studies that were not designed to examine the drugs' effects on the heart. Until such research is done, doctors should use caution in prescribing them to patients with heart disease, Topol said."
121	Sept. 4, 2001	You and A: Arthritis Drugs; Pain and Confusion	The Washington Post	"An article in the Aug. 22/29 issue of the Journal of the American Medical Association (JAMA) suggested that popular arthritis drugs Vioxx and Celebrex may increase the risk of cardiovascular events – including heart attacks, strokes and chest pain." "One study showed twice as high a rate of cardiovascular events for people taking Vioxx as for those who took naproxen, another pain reliever." "What isn't clear is whether Vioxx increased risk by causing blood platelets to clump together and thereby promoting a clot, or whether naproxen protected some people from heart attacks by keeping platelets from clumping together."

Ex. No.[1]	Date	Title	Publication	Excerpts
September 17, 2001 – FDA Issues Warning Letter to Merck				
122	Sept. 24, 2001	Merck Misrepresents Safety of Vioxx, FDA Says in Warning Letter	Bloomberg News	"The U.S. Food and Drug Administration cited Merck for minimizing 'potentially serious' findings in a study that showed heart attacks were significantly more common among patients who took Merck's drug than in patients who were treated with a older generic painkiller called naproxen."
123	Sept. 24, 2001	Merck Vioxx Promotions Said Misleading on Safety	Reuters News	"U.S. regulators have charged drug giant Merck and Co. Inc. with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks." "The Food and Drug Administration, in a warning letter sent Sept. 17 and released publicly late Friday, ordered the company to stop using some promotional materials and to send a letter to healthcare providers to correct any false impressions." Vioxx and other similar drugs may themselves independently increase risks of blood clots."

Ex. No.[1]	Date	Title	Publication	Excerpts
124	Sept. 25, 2001	FDA Sends a Warning Letter to Maker of Vioxx Painkiller	USA Today	"The Food and Drug Administration has ordered Merck, maker of the blockbuster painkiller Vioxx, to issue a letter to doctors 'to correct false or misleading impressions and information' stemming from the drug's promotional campaign." "Merck's marketing efforts, aimed mainly at doctors, have minimized Vioxx's known and potential cardiovascular risks, the FDA wrote in an eight-page 'warning letter' faxed Sept. 17 to Raymond Gil-martin, president and chief executive officer. The letter, signed by Thomas Abrams, head of the FDA's Division of Drug Marketing, Advertising and Communications, was posted Friday on the FDA Web site."

Ex. No.[1]	Date	Title	Publication	Excerpts
125	Sept. 25, 2001	Merck Slips after FDA Scolding on Vioxx Safety Claim	Reuters News	"Shares of Merck & Co. fell on Tuesday after U.S. regulators accused the firm of making unsubstantiated claims about its hot-selling arthritis drug Vioxx and downplaying a possible risk of heart attack from taking the medicine." "[N]oted cardiologists, including Eric Topol of the Cleveland Clinic, received widespread attention last month with a report suggesting Vioxx and rival arthritis drug Celebrex, sold by Pharmacia Corp., might independently increase the risk of heart attack and stroke by themselves causing blood clots."
126	Sept. 25, 2001	Vioxx: FDA Warns Merck About 'Misleading' Ads	American Health Line	"USA Today reports that in a clinical trial of 4,000 patients, researchers found that those taking Vioxx were 'more than twice as likely' to suffer a 'serious cardiovascular complication' as those taking the NSAID naproxen." "In the warning letter, the FDA says, 'In fact, the situation is not at all clear' and adds that 'no adequate and well-controlled studies' exist to support Merck's theory."

Ex. No.[1]	Date	Title	Publication	Excerpts
127	Sept. 25, 2001	FDA Says Merck Misleading on Vioxx Safety	The Associated Press	"The main issue: Whether Vioxx users face an increased risk of heart attacks and strokes. A recent study comparing Vioxx to another painkiller, naproxen, suggested they do. Many heart experts are divided about the risk and want more research." "'In fact, the situation is not at all clear,' the FDA responded, saying no studies prove naproxen thins blood enough to explain the discrepancy."

Ex. No.[1]	Date	Title	Publication	Excerpts
128	Sept. 25, 2001	FDA Warns Merck for Vioxx Promotions	The Wall Street Journal	"The FDA's most recent concerns deal with a major clinical trial in which a higher rate of heart problems was observed in Vioxx patients than in patients on a more traditional nonsteroidal anti-inflammatory drug, naproxen." "The FDA said that the exact reason for the increased rate of heart problems isn't known, but that the Merck promotional campaign 'selectively' presented the hypothetical explanation that drugs used in comparisons with Vioxx help prevent heart problems--thus making Vioxx's rate of heart problems appear to be artificially inflated. "The FDA says that, 'In fact, the situation is not at all clear' and that there are 'no adequate and well-controlled studies' to support Merck's assertion."

Ex. No.[1]	Date	Title	Publication	Excerpts
129	Sept. 26, 2001	National Briefing Science and Health: U.S. Warns Merck About Marketing Arthritis Drug	The New York Times	"A recent study comparing Vioxx to another painkiller, naproxen, suggested that Vioxx users faced an increased risk of heart attacks and strokes, but many heart experts want more research. Still, an F.D.A. advisory panel has said Vioxx should carry a warning label about the potential risk."

Ex. No.[1]	Date	Title	Publication	Excerpts
130	Sept. 29, 2001	18 Utahns Sue Pharma-ceutical Giant over Vioxx	Deseret News	"Eighteen Utahns have filed a personal injury lawsuit against pharmaceutical giant Merck & Co., alleging the company misrepresented the risks associated with the prescription drug Vioxx." "The people claim in a lawsuit filed in 3rd District Court Friday they suffered ailments ranging from strokes to heart attacks to death after taking Vioxx." "[The plaintiffs' attorney] said his firm is working with a California firm that has filed an individual and class-action suit against the company. That firm has associations with similar actions in Arizona, Colorado, Nevada and Wisconsin."

Ex. No.[1]	Date	Title	Publication	Excerpts
131	Oct. 3, 2001	Utah Residents Suing Arthritis-Drug Maker	Associated Press Newswires	"More than a dozen Utah residents are suing a drug company for allegedly downplaying the health risks of an arthritis drug they say triggers heart attacks and strokes." "At issue is a widely reported research finding that Vioxx may be linked to an increase in the risk of cardiovascular problems such as heart attack, stroke and angina, severe chest pains caused by an oxygen-starved heart." "Many critics say the findings are flawed because the Journal of the American Medical Association study was a compilation of earlier studies that didn't address the cardiovascular-risk questions surrounding Vioxx."

Ex. No.[1]	Date	Title	Publication	Excerpts
132	Oct. 9, 2001	For Pain Reliever, Questions of Risk Remain Unresolved	The New York Times	"[S]ome heart specialists say they are now telling patients that they may want to consider taking other drugs for pain." "But a few years ago, Dr. Garret FitzGerald, a University of Pennsylvania scientist, raised a theoretical question: can cox-2 inhibitors shift a biochemical balance so that blood will be more likely to clot? If so, patients taking cox-2 inhibitors may be at greater risk for heart attacks and strokes. As a consequence, said Dr. Edward Scolnick, the president of Merck Research Laboratories, the company decided to look specifically for excess heart attacks and strokes in a new study it was designing." "[VIGOR] found that the patients taking naproxen had just one quarter the number of heart attacks of those taking Vioxx. Twenty Vioxx patients, 0.5 percent, had heart attacks, compared with four, or 0.1 percent who took naproxen. "'There are two possible interpretations,' Dr. Scolnick said. 'Naproxen lowers the heart attack rate, or Vioxx raises it.' . . . [N]ow that the clotting questions have been raised, none of the findings to date are enough to prove that the issue is fully resolved. That lack of proof is why the F.D.A. demanded that Merck explain both sides of the hypothesis, telling doctors

Ex. No.[1]	Date	Title	Publication	Excerpts
				and patients that it is not known whether naproxen protects against heart attacks or Vioxx makes them more likely." "[W]hile the company announced the heart attack findings to doctors and the public, it looked back at its data from studies using different drugs or dummy pills in comparison to Vioxx." "On the other hand, Dr. Scolnick said, now that the clotting question has been raised, none of the findings to date are enough to prove that the issue is fully resolved. That lack of proof is why the F.D.A. demanded that Merck explain both sides of the hypothesis, telling doctors and patients that it is not known whether naproxen protects against heart attacks or Vioxx makes them more likely."

SAMPLE ANALYST REPORTS IN 2000 AND 2001

Ex. No.[1]	Date	Title	Source	Excerpts
March 27, 2000 – VIGOR Results Announced				
133	Mar. 27, 2000	VIOXX GI Outcomes Trial—GI Safety Excellent, Side Effects Looming	Salomon Smith Barney	"Bad News: Unexpectedly, Vioxx had a higher rate of cardiovascular side effects (such as thromboembolic events) than naproxen... Did long-term exposure to high-dose Vioxx produce significant side effects? If so, side effects could emerge as more of a commercial problem for Vioxx vs. Celebrex..."

[1] Exhibits referenced in this composite exhibit are attached to the Declaration of Robert H. Baron, dated August 12, 2005, in support of Defendants' Motion to Dismiss the Corrected Consolidated and Fourth Amended Class Action Complaint.

Ex. No.[1]	Date	Title	Source	Excerpts
134	Mar. 28, 2000	Pharmaceutical Industry: Merck's VIGOR Trial Confirms Vioxx's GI Safety	JPMorgan Americas	"There is substantial clinical evidence to easily support that [the VIGOR cardiovascular data] is likely due to a beneficial cardiovascular effect of Naproxen, not a risk of Vioxx... However, a significant statistical difference between the two drug classes (for reduced cardiovascular events) has not been seen in previous studies. This might be an issue of controversy worth watching with the FDA. Ultimately, we believe Vioxx will escape damage." "Even though the FDA might permit a label change pertaining to the standard NSAID warning on Vioxx's label... it may also include some caution with regard to higher cardiovascular events relative to those observed with the use of NSAIDs."

Ex. No.[1]	Date	Title	Source	Excerpts
135	Apr. 17, 2000	Industry: Celebrex Class Trial Confirms G.I. Safety (With a Slight Wrinkle) – No Cardio-vascular Risk	JPMorgan Americas	"For Vioxx, although medical intuition implies the thromboembolic event issue is an 'NSAID-issue,' the theoretical cardiovascular protective benefits of Naprosyn (the VIGOR comparator NSAID) have not been clinically proven, and the non-aspirin using cut of CLASS did not show the same [cardiovascular] problem for Celebrex."
136	Apr. 24, 2000	MRK vs. PHA: COX-2 Inhibitor GI Outcomes Data at DDW May 20-26	Salomon Smith Barney	"In VIGOR Vioxx made primary (PUBs) and 2nd endpoint (POBs) because it barred co-admin of aspirin, but Vioxx was associated with thromboembolic events... [A]ssociation with thromboembolic events could be Vioxx 'Achilles heel.'"

Ex. No.[1]	Date	Title	Source	Excerpts
137	Apr. 28, 2000	Reiterating a hold on Merck	Street Advisor	"Potential safety issues with Merck's [MRK] Vioxx drug could prove hazardous to the company's health. Any potential shortfall in expected Vioxx sales would have a definite impact on Merck's ability to maintain its current growth rate as it faces several patent expirations over the next few years..." "Vioxx, which is expected to have sales well in excess of $1bn this year, is receiving scrutiny after studies show that patients taking the drug had significantly more heart attacks and strokes than patients taking naproxen..." "[T]he real risk is if the drug is restricted for all indications. Vioxx is the star drug in Merck's lineup, and the loss of sales would be a big blow to its prospects. The outcome of this news is very uncertain at this point. Investors should be concerned because the FDA seems to be scrutinizing drugs with any potential safety issues much more closely."

Ex. No.[1]	Date	Title	Source	Excerpts
138	May 1, 2000	Daily Research Highlights: Monday, May 1, 2000	Deutsche Banc Alex. Brown	"Confusion over MRK's Vioxx VIGOR Results... The issue giving investors ulcer bleeds with the Vioxx data related to the misinformation circulating that Vioxx showed an increased incidence of thromboembolic events (stroke, heart attack) in the VIGOR trial. The facts are that Vioxx was associated with a very low risk associated with cardio-events of less than 1/10 of 1%, which is consistent with the current label. However, Naproxen was associated with a statistically significantly lower number of thromboembolic events, due probably to it inhibition of COX-1... We believe the market's reaction to this news is an overreaction..." (p. 22)

Ex. No.[1]	Date	Title	Source	Excerpts
139	May 1, 2000	Global Healthcare Bulletin	Merrill Lynch	"Vioxx Speculation Seems Overdone... Merck stock has reacted negatively to speculation concerning the company's drug Vioxx. News reports suggested that the FDA may scrutinize the data recently released from the VIGOR study (Merck's GI outcomes study) after an increased rate of cardiovascular events was seen versus the comparator drug Naproxen... Unless the incidence of events is higher for Vioxx than placebo (or other NSAIDs) or Vioxx is suspected of actually causing events then we would not expect the FDA to take issue with the drug... The study may simply be reflecting a positive effect of Naproxen (which may also have a more positive effect than other less potent NSAIDs) rather than a negative effect of Vioxx." (p. 39)

Ex. No.[1]	Date	Title	Source	Excerpts
140	May 2, 2000	US Pharma Focus	Goldman Sachs	"What has attracted more attention [than the VIGOR GI results] is the finding that there were significantly fewer thromboembolic events in the naproxen group. While naproxen is known to inhibit platelet aggregation (or 'clumping' that can lead to the formation of clots in arteries), it has never been shown clinically that naproxen prevents heart attacks in the way that aspirin, another platelet inhibitor, does." (p. 4)

Ex. No.[1]	Date	Title	Source	Excerpts
141	May 8, 2000	Merck & Co. Falters on Vioxx Cardio-vascular Events, Fules Competition with [*sic*]	Pharma Market letter	"Details of preliminary data from a study of Merck & Co's blockbuster COX-2 inhibitor Vioxx (rofecoxib) may mean the company will be questioned by the US Food and Drug Administration, according to CNBC and Reuters reports... Shares in Merck faltered on the news, dropping 2.8% on April 28 to close at $69.50." "Analysts are split about the [VIGOR] study. The heart attacks and strokes could be a serious concern for the FDA, and could delay or derail plans to market Vioxx for rheumatoid arthritis, according to David Saks of Gruntal & Co. The issue could also affect the drug's total sales, he added, having previously forecast Vioxx annual turnover of $2 billion by 2002 including $200-300 million in rheumatoid arthritis sales."

Ex. No.[1]	Date	Title	Source	Excerpts
142	May 24, 2000	Merck/-Pharmacia: Merck Presents Vigor Trial at DDW	JPMorgan Americas	"On cardiovascular safety, the risk of suffering a heart attack among Vioxx patients was 0.4%, versus 0.1% among naproxen patients, a statistically significant increase, which had been previously reported as well. Since there was no placebo arm in this trial, it is impossible to determine if Vioxx patients had an increased risk of suffering heart attacks, or if naproxen patients had a decreased risk."

Ex. No.[1]	Date	Title	Source	Excerpts
143	May 26, 2000	First Call	ABN-Amro	"We are puzzled by the Vioxx MI issue, which could draw FDA ire. MRK has argued that the higher MI incidence relative to Naproxen (0.4% vs. 0.01%) is a result of a cardiovascular benefit of naproxen, not due to harmful effects of Vioxx. However, there have not been any clinical studies demonstrating a cardiac benefit of naproxen..." "In our opinion, the new Vioxx information appears plausible, but the inconsistency remains that in previous Celebrex trials versus naproxen, there was no increase in MI reported, with or without aspirin use... Thus we are not convinced that this will be an open and shut case when the FDA reviews the data when it is filed this quarter."

Ex. No.[1]	Date	Title	Source	Excerpts
144	June 2, 2000	Cox-2 Inhibitor Update: Vioxx Cardio-vascular Safety Issues Unresolved; GI Safety Trials Presented At Annual Digestive Disease Week Meeting	Arnhold and L. Bleich-roeder	"[W]e remain concerned that VIGOR shows high-dose (50mg) Vioxx treatment is associated with a higher risk of heart attack, and we would anticipate that this could be added to the Vioxx label warnings." (p. 6) "Merck's suggestion that naproxen would be expected to be more cardioprotective than ibuprofen and diclofenac simply doesn't hold much water... In our view, Merck has *not* made the case that VIGOR provided the first demonstration of cardioprotection with naproxen in over a quarter of a century of clinical experience. Rather, it appears far more likely that VIGOR shows a dose-dependent increase in CV risk associated with Vioxx..." (p. 7)

Ex. No.[1]	Date	Title	Source	Excerpts
145	Dec. 1, 2000	Equity Research – Pfizer, Inc.	CSFB	"The surprise in the Vigor trial involved a higher incidence of heart attack observed in the Vioxx arm of the clinical trial versus Naproxen." (p. 21)
146	Jan. 11, 2001	Preview of FDA meeting on Celebrex	Swedbank Markets	"Merck also experienced an unpleasant surprise in its VIGOR study. Patients who took Vioxx significantly increased the risk of a myocardial infarction compared to patients who took older drug naproxen. This unexpected result adds to Vioxx's previously reported, rare side effects... The VIGOR results should lead to the FDA demanding supplementary studies on Vioxx regarding the risk of myocardial infarction." (p. 2)

Ex. No.[1]	Date	Title	Source	Excerpts
147	Feb. 2, 2001	Pharmaceuticals Industry: Expect FDA COX-2 Label Changes	JPMorgan Americas	"The controversy for Vioxx is that it showed a statistically higher rate of heart attack (MI) than the NSAID comparator... Since there was no placebo arm in this trial, it is impossible to determine if Vioxx patients had an increased risk of suffering heart attacks, or if NSAID patients had a decreased risk." "[W]e are a touch more concerned about this finding because: (a) there is also a documented theory regarding the potential for thromboembolic risk with COX-2s; (b) there is no way to retrospectively slice the data to test whether it is an NSAID benefit or a Vioxx risk; and (c) this is the type of clinical 'signal' that was first ignored, and later haunted the FDA in drug recalls."

Ex. No.[1]	Date	Title	Source	Excerpts
148	Feb. 7, 2001	Cautious on MRK Shares Ahead of FDA Meeting on Vioxx Tomorrow	Bear Stearns	"We are cautious on Merck shares in the short-term due to uncertainties surrounding the outcome of today's FDA Advisory Committee meeting to discuss revised labeling for their blockbuster anti-inflammatory Vioxx... Merck will need to answer questions about significantly higher levels of cardiovascular adverse events for Vioxx versus Naproxen seen in VIGOR. The outcome and tone of yesterday's Celebrex meeting leads us to believe there is added risk that Vioxx will not receive better [GI] labeling. Combined with a possible recommendation for addition of a cardiovascular warning to Vioxx's label, we expect Merck shares to remain volatile until this issue is resolved."

Ex. No.[1]	Date	Title	Source	Excerpts
February 8, 2001 – Arthritis Advisory Committee Hearing				
149	Feb. 8, 2001	Vioxx Label Change Meeting Update	Bear Stearns	"The [FDA Advisory Committee] stated their desire to add 'what was learned' through the VIGOR study to the Vioxx label. However, the committee also felt any label additions should directly cite the VIGOR trial data, i.e. Vioxx vs. naproxen comparisons... We expect any label changes to refer very specifically and rigidly to VIGOR study results... Merck presented clinical and anecdotal evidence pointing to the cardioprotective effect of naproxen as the cause of this result, citing naproxen's similarity to aspirin, a known cardioprotectant. A meta-analysis of both VIGOR and previous NDA clinical data also pointed towards naproxen as the 'problem', not Vioxx. FDA personnel and some of the committee refuted this hypothesis, noting that naproxen would need to provide a level of cardioprotection higher than aspirin for this hypothesis to be correct. FDA personnel also noted that the higher level of cardiothrombotic AE's for Vioxx were a counterbalance for the reduced gastrointestinal AE's, leading to a similar level of overall safety for Vioxx compared to Naproxen..."

Ex. No.[1]	Date	Title	Source	Excerpts
150	Feb. 8, 2001	Merck: A Rough Ride In Store For Vioxx After Celebrex Hammered	JPMorgan Americas	"The hornet's nest for Vioxx will be the higher incidence of severe cardiovascular adverse events (including heart attacks) which the FDA views as related to a real Vioxx risk, rather than exclusively an NSAID benefit in the naproxen arm of VIGOR. Celebrex appeared quite clean in this regard... For both products, resulting label revisions may wind up slightly worse, rather than better. While we expect that the data from each company's trial will appear in the label, each has its warts... Any Vioxx-specific cardiovascular warnings would be significantly detrimental, in our view." "Today's review of VIGOR—Committee likely to Pounce on Increased Cardiovascular Risk... Merck has argued that it was the antiplatelet effect of naproxen that effectively reduced the incidence of cardiovascular events in the VIGOR trial. The FDA reviewers dismissed this explanation because (1) naproxen has never been shown to impact cardiovascular outcomes; and (2) the benefit seen for naproxen over Vioxx is about double the benefit of aspirin over placebo for preventing cardiovascular events, a highly unlikely scenario."

Ex. No.[1]	Date	Title	Source	Excerpts
151	Feb. 9, 2001	Slight Positive For MRK As FDA Panel Recommends Changes To Vioxx Label	SG Cowen	"Possible enhanced cardiovascular warnings a negative for Vioxx...The [Advisory Committee] panelists questioned whether there was a low rate of cardiovascular events in the Naproxen group or high rate in the Vioxx group. The lower rate of cardiovascular events could have been due to Naproxen's cardioprotective effect, lack of cardioprotective effect from Vioxx, or both. Other questions the committee raised include: (1) does Vioxx increase cardiovascular events versus placebo? (2) can we neutralize negative cardiovascular effect by giving low-dose aspirin, without offsetting benefit by reduced GI safety? (3) what level of cardioprotection can be achieved by NSAIDS? These questions require further studies." "[The Advisory Committee voted] Yes (10-1 vote), there should be some mention of VIGOR's cardiovascular data [on the VIOXX label]. The panelists believed that there was an excess in cardiovascular events in the Vioxx group versus Naproxen, but it is unclear whether the reason is Naproxen's cardioprotective effect or a negative impact from Vioxx."

Ex. No.[1]	Date	Title	Source	Excerpts
152	Feb. 9, 2001	Equity Research - A Weekly Dose of Pharmaceutical News	CIBC World Markets	"FDA's Arthritis Advisory Committee recommended a modification of Vioxx's label to include data from the VIGOR trial, reflecting improved upper gastrointestinal safety as well as a higher incidence of adverse coronary events vs. naproxen in the trial population." (p. 3)
153	Feb. 14, 2001	US and the Americas Investment Perspectives	Morgan Stanley Dean Witter	"A majority of the [FDA] panel recommended that the FDA amend Vioxx's label to include the results of the VIGOR trial. And while the advisory panel was neither decisive nor conclusive in its recommendation, the prevailing opinion was that the VIGOR trial's results (both good and bad) were significant and needed to be communicated to the broader medical community. This likely means the following for Merck's label... It will likely include a clause that references its higher rate of thrombotic events versus naproxen (and only naproxen) in patients not taking aspirin..." (p. 65)

Ex. No.[1]	Date	Title	Source	Excerpts
154	Apr. 11, 2001	'Approvable' Letter for Vioxx Safety Label Expansion	Lehman Brothers	"Additionally, another major topic of discussion with the Panel concerned the increased cardiovascular risk associated with Vioxx use. Specifically, the study results showed that naproxen usage was associated with a 58% lower risk for the development of thrombotic cardiovascular serious events (e.g. heart attack or stroke) compared with Vioxx treated patients. While not statistically significant, there was a negative trend towards Vioxx. While the panel agreed that it was unclear what the source of this increased risk associated with Vioxx usage was due to, the separation between naproxen and Vioxx was deemed significant enough to be highlighted in some context. Thus, the panel voted 10 to 1 in favor of recommending including additional language in the label pertaining to this increased cardiovascular risk. We expect this additional language to likely be placed in the precaution section and perhaps only be in the context of at-risk patients (e.g. patients with a predisposition and/or history of cardiac illness). Additionally, the wording may not isolate Vioxx as much as it might reference the uncertainty of COX-2 inhibitors in increasing thrombotic events. All were in agreement that the topic warranted additional study."

Ex. No.[1]	Date	Title	Source	Excerpts
				"[T]he Panel discussed at length the overall, or 'global' safety of Vioxx as shown by the VIGOR study. There was considerable debate over the risk/ benefit of Vioxx, specifically GI benefit versus CV risk. There was no unanimous conclusion reached on what the overall safety of the study showed. In fact, this question may have provoked the most disagreement among Panel members."

Ex. No.[1]	Date	Title	Source	Excerpts
155	Apr. 27, 2001	COX-2 Inhibitor Outlook: Cardiovascular Safety Issues Raised in FDA Advisory Committee Meetings	Arnhold and L. Bleichroeder	"Public disclosures from the FDA Advisory Committee meetings contain disturbing data, showing marked differences between naproxen and Merck's Vioxx in the incidence of serious cardiovascular events... Our analysis suggests that naproxen did not show cardioprotection in the VIGOR trial." "The discussion among the FDA committee members reflected conflicting points of view as to how to interpret the data and what the FDA should do about relabeling... For us, the discussion raised more questions than answers, and it became evident that we needed to scrutinize the data more closely." "At this juncture, the FDA's actions with respect to these issues by no means remain clear. The FDA's briefing documents do reveal that the FDA reviewers share our concerns, but perhaps not to the same degree. And the committee members expressed highly divergent views with respect to product labeling changes that the FDA should consider..."

Ex. No.[1]	Date	Title	Source	Excerpts
156	May 22, 2001	Negative Story In New York Times On Merck's VIOXX	Dain Rauscher	"There is a negative story in the NY Times relating to the coxib class of analgesics, comprised of Merck's Vioxx and Pharmacia Corp.'s Celebrex, that questions their safety profiles. We do not believe the story contains any new information..." "Some physicians are calling into question the safety of the class, and are trying to push the FDA to require a warning label associating Vioxx with a 'supposed' higher risk of heart attack."

Ex. No.[1]	Date	Title	Source	Excerpts
157	June 22, 2001	Slightly Lowers EPS Guidance; Downgrading From Buy to Market Perform	Tucker Anthony Sutro	"We are concerned that the slowing of Vioxx may be the harbinger of something more serious. Merck recently reported on long-term studies comparing the safety of Vioxx, to an older non-steroidal anti-arthritic agent naproxen. Merck was attempting to establish that Vioxx had a better gastrointestinal side effect profile. While this was shown, the study also revealed that Vioxx was associated with more cardiovascular events than naproxen." "Because osteoarthritis and rheumatoid arthritis occurs in patients who are also likely to have cardiovascular problems, this is potentially a significant disadvantage for Vioxx against Celebrex and older NSAIDs."
158	June 25, 2001	MRK(RL): Lowering Guidance, Reiterate RL	Goldman Sachs	"Merck's Vioxx has clearly come under scrutiny owing to the higher rates of heart attack when compared to naproxen seen in the VIGOR study. That said, Merck's data shows no heart attack signal in any placebo-controlled trial. But in our opinion this could become a perception issue for both drugs."

Ex. No.[1]	Date	Title	Source	Excerpts
159	June 25, 2001	Bounding the COX-2 Inhibitor Issue	Morgan Stanley Dean Witter	"While VIGOR proved Vioxx's GI superiority vs. Naproxen, its safety profile is not without controversy. Although the study did not intend to specifically address cardiovascular issues, Vioxx was associated with a greater incidence of myocardial infarctions (in patients not taking aspirin). We believe that the FDA will require MRK to incorporate this finding in the label, and as a result, will become a key message that will need to be explained away in physician details."
August 22, 2001 – JAMA Article Published				
160	Aug. 22, 2001	Equity Research - JAMA Study Could Pressure Vioxx: Maintain Hold	CIBC World Markets	"A new study published by the Journal of the American Medical Association suggests that patients taking VIOXX, MRK's popular COX-2 inhibitor for arthritis and pain, have a higher incidence of heart attack than the comparator... The JAMA study falls short of being conclusive but does suggest to us that gaining additional large shares of market against NSAIDs will be difficult."

Ex. No.[1]	Date	Title	Source	Excerpts
161	Aug. 22, 2001	JAMA Article Focuses on the Potential Increased Cardio Risks of COX-2's, Further Penetration of NSAID Market Limited	Deutsche Banc Alex. Brown	"[The JAMA article] 'raises a cautionary flag about the risk of cardiovascular events with COX-2's, and mandates that a trial specifically addressing the cardiovascular risk and benefit of these drugs be conducted, particularly in light of their remarkable exposure and popularity. The authors freely admit the limitations of their post-hoc analysis..." "FDA will likely require... longer term studies to further define the cardiovascular risk profiles of Vioxx, and Celebrex... [Q]uestions are already being raised about whether these drugs really do offer an improved risk profile, or whether they reduce the GI events, but raise the cardio risk. So, [the JAMA article] is not new news, and is unlikely, therefore, in our opinion, to reduce sales."

Ex. No.[1]	Date	Title	Source	Excerpts
162	Aug. 22, 2001	JAMA COX-2 Study Possesses Considerable Limitations	CSFB	"An article in the current edition of the Journal of the American Medical Association (JAMA) recommends a cardiovascular study on the currently available COX-2 inhibitors (Merck's Vioxx and Pharmacia/Pfizer's Celebrex) as well as prescribing caution in patients at risk for cardiovascular events... We note that our forecasts have already been adjusted for a relative slower rate of penetration of these drugs."

Ex. No.[1]	Date	Title	Source	Excerpts
September 17, 2001 – FDA Issues Warning Letter to Merck				
163	Sept. 24, 2001	Merck's Vioxx: FDA Vigilant on Cardio-vascular Risks	Merrill Lynch	"The FDA issued a warning letter to Merck on September 17th (that was subsequently posted 9/21 on the FDA website) concerning the promotion of Vioxx and a press release by Merck concerning Vioxx. The primary issue that the FDA has with the promotion of Vioxx is Merck's explanation as to why naproxen has a lower rate of myocardial infarction than that of Vioxx in the Vigor study. The FDA points out that the reason why heart attack rates are lower in naproxen and higher in Vioxx have not been adequately studied. While Merck attributes this difference to the platelet inhibition of naproxen, the FDA pints out that it is also possible that Vioxx has pro-thrombotic properties. The FDA is looking for Merck to cease all violative promotional activities... It would appear that Merck will have to be more balanced in its presentation of why the MI rates are higher in Vioxx."

Ex. No.[1]	Date	Title	Source	Excerpts
164	Sept. 25, 2001	Equity Research - FDA Warning on Vioxx Sparks Sell-Off	CIBC World Markets	"Although warning letters for promotions are fairly common, the severity amid the heightened sensitivity to potential cardiovascular issues has taken the shares down almost 5% today." "The letter renews concerns of added warning to the label, complicating market share expansion for COX-2's. Our view, dating back to the disclosure of VIGOR, is that the positive (lower GI bleeding) as well as the negative (potential cardiovascular risk) will both be incorporated into Vioxx's label." "The FDA warning letter as well as a recent JAMA article raising concerns of cardiovascular risk will continue to pressure the stock, now trading close to its 52-week low. With the shares trading at just 16x our preliminary EPS estimate of $3.83, the shares appear to fully represent investor concerns."

Ex. No.[1]	Date	Title	Source	Excerpts
165	Sept. 25, 2001	Merck Receives Warning Letter from FDA on VIOXX	CSFB	"Recent prescription trends have indicated that adverse publicity and cardiovascular concerns have contributed to erosion in Vioxx (as well as Celebrex) market share within the collective COX-2/NSAID market." "The [September 17, 2001 warning] letter objects to Merck's assertion that the higher rate of myocardial infarction (MI) observed in Vioxx patients versus those on the comparator generic painkiller Naproxen in the VIGOR clinical trial was attributable to the fact that naproxen has a similar cardioprotective profile to aspirin. The FDA notes that while this hypothetical explanation is plausible, Merck's failure to disclose publicly the fact that it is hypothetical or back the statement with substantial evidence was unacceptable. The FDA warning letter further cites an alternative proposition that the increased rate of MI's observed in the Vioxx treatment group may be tied to possible Vioxx pro-thrombotic properties."

Ex. No.[1]	Date	Title	Source	Excerpts
166	Sept. 25, 2001	FDA Warns Merck for Vioxx Marketing Practices	Dain Rauscher	"It is likely that the[] issues [raised in the September 17, 2001 warning letter] are already common knowledge in the medical community, with any adjustments to the drug regimens of at-risk patients largely in place. In February, new clinical data for Vioxx was reviewed by an FDA advisory committee; and, while cardiovascular safety was an acknowledged concern and a significant topic of discussion, no labeling changes were recommended. In addition, a recent (August 22) article in the Journal of the American Medical Association described a re-analysis of existing clinical data, and concluded that further studies addressing cardiovascular safety are warranted. Finally, this issue was raised in a New York Times article in May."

Ex. No.[1]	Date	Title	Source	Excerpts
167	Sept. 25, 2001	Spanked by DDMAC Over Vioxx Promotion	Lehman Brothers	"[T]he fact that MRK is awaiting final approval for a label expansion for the GI safety of Vioxx makes the scrutiny of this [warning] letter and its possible implication on that label change very high." "We do not debate that MRK may have violated several DDMAC codes. In fact, we are largely in agreement with the notion that the discrepancy in CV effects between naproxen and Vioxx are likely related to naproxen's ability to block platelet aggregation rather than Vioxx's propensity to promote platelet aggregation (we suspect Vioxx is neutral). Ultimately, however, the absolute effect of Vioxx on CV safety is unknown. Hence, if MRK were to suggest otherwise, as the DDMAC has asserted, it certainly would be in violation of strict FDA regulations."
168	Sept. 25, 2001	Research Note – FDA Warns Merck on Vioxx	UBS Warburg	"FDA issues warning to Merck for marketing only one side of the Vioxx safety argument... Vioxx cardiovascular safety debate continues... Since [the February 2001 Advisory Committee meeting], there has been an on-going debate as to whether [the VIGOR] result was due to Naproxen being

Ex. No.[1]	Date	Title	Source	Excerpts
		Marketing		'cardioprotective,' thereby having below average risk, while Vioxx has average risk, OR that Naproxen has average risk for the class, while Vioxx has above average risk." "Merck may have no choice but to do another study. The FDA's position appears similar to our own, which is that the data available to date are simply not definitive. We do believe that the only way to resolve this issue is to undertake a safety study with a true cardiovascular risk endpoint. Merck has never agreed to do this, but it may have no choice." "Safety concerns negatively impacting prescriptions. The continued negative publicity has been hurting prescription trends for the COX-2 family... for several weeks since the publication of a negative article in the August 22nd issue of JAMA."
169	Oct. 2001	Pharmaceutical Therapeutic	SG Cowen	"[I]t appears that Vioxx's label may reflect superior language in terms of gastrointestinal safety than Celebrex. This may be offset by additional discussion of cardiovascular safety... We

Ex. No.[1]	Date	Title	Source	Excerpts
		Categories Outlook		believe these changes will confirm in physicians' minds what is already known about coxibs..." (p. 54) "JAMA illustrated the possible link between the coxibs and an abnormally high rate of cardiovascular adverse events..." (p. 56) "VIGOR... left lingering questions on cardiovascular safety... The [February 2001 Advisory Committee] panelists questioned whether there was a low rate of cardiovascular events in the [VIGOR] Naproxen group or high rate in the Vioxx group. The lower rate of cardiovascular events could have been due to Naproxen's cardioprotective effect, lack of cardioprotective effect for Vioxx, or both... The cardiovascular findings warrant consumer/provider awareness... The Committee believed that further studies were necessary to definitely prove whether Vioxx, Celebrex or the coxib class in general are associated with a higher risk of cardiovascular events." (p. 56, 57)

Ex. No.[1]	Date	Title	Source	Excerpts
170	Oct. 22, 2001	Not All Sales are Created Equal	Morgan Stanley	"Controversy about Vioxx's cardiovascular safety is weighing on market share and growth."
171	Nov. 29, 2001	MRK Responds to DDMAC Warning with Dear Doc Letter (Nov 19)-No Change to Vioxx or EPS	Deutsche Banc Alex. Brown	"[T]he FDA requested that MRK correct its promotional claims for Vioxx relating to the cardio issues. MRK has corrected the promo activities saying 'Alternative interpretations have been proposed for the difference in the rates of MI in the Vioxx treatment group in comparison with the naproxen treatment group in the VIGOR study. Possible explanations include that Vioxx increased the MI rate or naproxen decreased the MI rate. The underlying reason for the differences has not been established in prospectively designed clinical studies.'"

Ex. No.[1]	Date	Title	Source	Excerpts
172	Jan. 22, 2002	Despite Weak Vioxx Sales, MRK "Makes the Numbers"	Deutsche Banc Alex. Brown	"In addition to the slowing coxib market in general, on November 19 Merck responded to the FDA's DDMAC warning by issuing two Dear Healthcare provider letters to 100 doctors and 2,000 pharmacists." "[O]verall script volumes have still not recovered to mid-2001 levels resulting from the damage of the JAMA publication in August of 2001 on the potential for increased cardiovascular risk with Vioxx therapy... Additional studies are necessary to fully characterize the cardiovascular issues, if there are any, for [Vioxx]."

ADDITIONAL INFORMATION FROM "SAMPLE PRESS ARTICLES" (BARON DECL. EX. 58) NOT INCLUDED IN DEFENDANTS' COMPOSITE CHART

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
88	***Biotech Week***, "Merck & Co., Inc.: Preliminary Results of Gastrointestinal Outcomes Study Presented," April 12, 2000.	"[S]ignificantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, ***which is consistent with naproxen's ability to block platelet aggregation. This effect on these events had not been observed previously in any clinical studies for naproxen."***[1] ***"Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects."*** As for result, Merck is notifying investigators...of protocol amendments to allow the addition of low-dose aspirin where appropriate. ***Medicines like aspirin and naproxen that significantly inhibit COX-1 block platelet aggregation and therefore have the potential to provide cardioprotection.***

[1] Unless otherwise indicated, emphasis has been added.

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
89	***Reuters News***, "Merck's Vioxx seen facing FDA scrutiny on heart attacks," April 27, 2000	***"Naproxen blocks platelet aggregation, it keeps them from clumping together. That's in the literature,"*** according to Merck spokesperson Jan Weiner.
91	***Bloomberg News***, "Merck Falls on Vioxx Concerns; Company Denies Risk," April 28, 2000.	***"Lehman Brothers analyst Toney Butler, who pointed the different rate of cardiac problems in a note to investors when the Merck study was released in March, said that any conclusions about a cardiac effect of Vioxx based on that data would be very premature. Butler called the data 'positive.'"***
92	***Reuters News***, "Merck falls on safety concerns from Vioxx arthritis trial." April 28, 2000.	***"[Chase Hambrecht & Quist analyst Corey] Davis said he remained quite confident about Vioxx' overall safety, however, because previous studies comparing it with other popular arthritis drugs, as well as with placebos, showed no difference in the incidence of heart attacks and other thromboembolic events..."*** ***"Hemant Shah, an independent New Jersey analyst, said he shared Merck's belief that Vioxx itself probably does not increase***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		heart attacks and other cardiovascular problems, but that naproxen patients probably had fewer attacks because the older drug likely has 'cardio-protective' traits."
93	*Dow Jones*, "Are the Feds Coming After Merck (MRK)?" April 28, 2000	***"[A]t least one analyst – and the company – said there's little to worry about. 'This whole thing has been overblown and taken out of context,' says Wall Street Journal All-Star analyst Jeff Chaffkin of PaineWebber. 'We had this data over four weeks ago. This is nothing new.'"*** ***"Perceptions about the prospects for Vioxx are the single most important factor in Merck's stock price."*** "Merck claims that naproxen probably protects patients against heart problems by preventing the accumulation of platelets that could form blood clots. Vioxx and other so-called Cox-II inhibitors do not block platelet aggregation and, therefore, should not be expected to reduce the incidence of cardiovascular problems."

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		"With Vioxx's future tied to the Feds, Merck's stock is bound to suffer from more indigestion, says Saks." ***"Everyone likes a clear window of growth." Smith is even more blunt: "Perceptions about the prospects for Vioxx are the single most important factor in Merck's stock price.'"***
95	***Reuters News***, "Vioxx, Celebrex aim to profit from improved safety labels," May 21, 2000	***"Merck attributed the [CV results from VIGOR] to naproxen's' presumed ability to prevent platelets from clumping together to form blood clots, saying there was not reason to believe that Vioxx itself caused heart attacks."*** ***"The FDA has a huge database from Merck, of 10,000 patients where there is no increased incidence of heart attacks with Vioxx, Dr. Eve Slater...said in an interview."*** ***"'The FDA is not concened about this issue to the best of my knowledge, to the extent they have seen the data we have.' Slater said."***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
96	*Reuters*, "UPDATE 1 – Vioxx shown safer on GI than older drug," May 24, 2000	***Merck attributed naproxen's better results in heart attacks to the older drug's presumed ability to prevent blood platelets from clumping together to form blood clots. It said no difference in heart attack incidents was seen in earlier trails that compared Vioxx to other standard arthritis drugs.*** ***Moreover, Merck said there was no significant difference in heart attacks between the Vioxx and naproxen groups in VIGOR, when excluding consideration of the 4 percent of the total study group that had previously suffered heart attacks, strokes, other cardiovascular incidence or had angioplasty or more serious medical interventions.*** ***Merck said, 'The reduction in heart attacks is consistent with naproxen's ability to block platelet aggregation.'*** ***Tony Butler of Lehman Brothers commented, "When you exclude consideration of the 4 percent who have previous cardiovascular incidents, the difference in heart attacks between the Vioxx and naproxen patients are less a problem that previously speculated.***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		I don't think it's and issue at all."
98	***Bloomberg News***, "Merck's Vioxx Unlikely to Cause Heart Problems, FDA Panel Finds," February 8, 2001	***"Merck & Co.'s Vioxx painkiller isn't likely to cause cardiovascular problems..., though panelists called for more study to see if there is any link between the drug and heart problems."*** The panel found that "The difference could be the result of a cardiovascular benefit taking naproxen." ***"The finding makes it less likely that Vioxx's label will carry a significant warning of heart attacks or other cardiovascular problems, which would limit the use of the drug in the highly competitive market that Vioxx shares with Pharmacia Corp.'s Celebrex."*** ***Steven Nissen, a panel member said, "This provides some reassurance that what we see, in effect, is a protective effect of naproxen."***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
99		
100	***PR Newswire***, "FDA Arthritis Advisory Committee Reviews Merck's Application for Revised Labeling of Vioxx® Based on Gastrointestinal Outcomes Study," February 8, 2001	***"Merck is confident that the data presented today support the excellent safety profile of Vioxx..."*** ***"Merck scientists said that VIGOR finding is consistent with naproxen's ability to block platelet aggregation by inhibiting COX-1 like aspirin..."***
101	***Bloomberg News***, "Merck Drug Should Note Heart Risk, Stomach Benefit, Panel Says," February 8, 2001	***"Differences in cardiac risk between Vioxx and naproxen appeared to result from a beneficial effect of naproxen, not a danger from Vioxx, said Nigel Harris, the panel's chairman..."*** ***Merck shares rose $1.12 to $82.97.***
102	***The Associated Press***, "Scientists: Arthritis painkiller Vioxx causes	"Partly, naproxen may thin the blood, much like aspirin used by heart patients to prevent blood clots, and thus using Vioxx instead ***deprived***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
	fewer ulcers than naproxen," February 8, 2001	patients of the other drug's side benefit."
103	***Reuters***, "UPDATE 3-U.S. panel urges label changes for Merck's Vioxx," February 8, 2001	"The panel was concerned that more Vioxx patients in Merck's trial had heart attacks and other cardiovascular problems that patients taking naproxen. But members said it was possible that Vioxx did no harm and that naproxen protected the heart, as Merck argued."
104	***The Star Ledger***, "Federal panel suggests more studies of Vioxx," February 9, 2001	***"A federal advisory panel yesterday determined Merck & Co.'s best-selling painkiller, Vioxx, isn't likely to cause heart problems, but urged regulators to consider additional studies to clarify the issue"***
106	***The New York Times***, "Doubts Are Raised on the Safety of 2 Popular Arthritis Popular A Drugs," May 22, 2001	***"Merck says the research does not show a problem with Vioxx. Instead, the company says, naproxen acted to reduce heart attacks by working much like aspirin."*** ***"Merck's scientists say that naproxen appears to help reduce heart attacks by stopping or slowing the production of a substance***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		called thromboxane." ***Eve Slater, senior VP of external policy for MRL, said, "Naproxen had a similar antiplatelet effect to aspirin..., and those people had fewer heart attacks."*** ***"Dr. Slater also said that Mr. Stover's report was flawed and biased in favor of Pharmacia."***
107	***The New York Times***, "Personal Health; Newest Painkillers Deserve a Closer Look." June 12, 2001	***"[I]t is important to distinguish between established risks and potentially false conclusions based on inadequate studies."*** ***"Since the biological activity of naproxen is like that of aspirin and ibuprofen, it is reasonable to assume that it too will protect against heart attacks."*** "Many doctors familiar with the biological activity of these drugs think the Merck study demonstrates what they have long suspected: that like aspirin and ibuprofen, naproxen protects against heart

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		attacks." ***"Cox -2 inhibitors are likely to have significant health-promoting effects beyond reducing the pain and disability of joint disorders and certain injuries. Like other [NSAIDs] taken regularly, cox-2 inhibitors are believed to decrease the risk of colon cancer, apparently, according to animal studies, by promotion the regression of polyps and preventing their development."***
108	***Los Angeles Times***, "Health Matters: When Hype Stands In for Solid Science," June 18, 2001	***But sometimes consensus is scary, especially when sellers of new treatments, tests, drugs and devices take to the airways to shape public opinion. Doctors are part of the public too. With help from the media, sellers sometimes promote treatments whether or not research has proved them effective. In 20 seconds Oprah can generate more demand for a medical procedure than one or two well-done clinical trials reported in the New England Journal of Medicine. Hype, promotion and public relations can overwhelm whatever science there is, and if there isn't any, they become a substitute.***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		The arthritis drug Celebrex and its cousin Vioxx, which is prescribed for arthritis as well as acute pain, show what can happen. Celebrex is now the sixth bestselling drug, generating more than ,$4 billion in sales since its debut in early 1999.
109	***Associated Press***, "Report suggests heart link with Celebrex, Vioxx, but critics say more research needed," August 21, 2001	"The popular and heavily promoted new arthritis drugs Vioxx and Celebrex have been linked by researchers to a small but troubling increase in the risk of heart attacks and strokes. ***Critics say the analysis is flawed and no cause for [alarm]"*** ***'It's inappropriate at this point to rush to a conclusion that these drugs pose a serious cardiovascular risk,' said Dr. Thomas Schnitzer, a Northwestern University rheumatologist. The analysis 'is very far from proof.'"*** ***"Vioxx manufacturer Merck & Co. . . . disputed the analysis and said [the] drug[] [is] safe."*** ***"Dr. Laura Demopoulous, Merck's senior director of cardiovascular clinical research, noted that the Vioxx study***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		involved patients with rheumatoid arthritis, a disease that raises the risk of heart trouble. She also said that the results may reflect naproxen's potential heart-friendly benefits rather than any negative effects from Vioxx."
110	***Bloomberg News***, "Merck, Pharmacia Pain Drugs Tied to Heart Attacks, Study Finds," August 21, 2001	***"We already have additional data beyond what they cite, and the findings are very, very reassuring,' said Laura Demopoulous.... 'Vioxx does not result in any increase in cardiovascular events compared to placebo.'"***
111	***Reuters News***, "Study sees heart attack risk in arthritis drug," August 21, 2001	***"The marketers of [Vioxx and Celebrex] disagreed with the findings [that suggest a potential CV risk for both drugs]... saying patient experience and other data showed they were safe."*** ***"Merck, which markets... Vioxx, said it 'stands behind the overall and cardiovascular safety profile' of the drug. It said extensive safety data not included in the new report suggests `that there is no increase in the risk of cardiovascular events as a result of treatment with Vioxx.'"***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
112	*Dow Jones News Service*, "Vioxx, Celebrex Use Raises Cardiovascular Concerns -- Study," August 21, 2001	***"Merck, Pharmacia and Pfizer counter the researchers suggestion [that the drugs increase the risk of heart attacks or other CV events].... The drug makers separately insist that their drugs are effective and safe, overall and with respect to the heart and cardiovascular system."*** ***"We can't explain what is behind that observation and the authors point out the lower rate of cardiovascular events in those receiving naproxen may be the result of the beneficial effect of naproxen, which has aspirin-like profile in preventing platelet aggregation' said Laura Demopoulous...."*** ***"Merck has created an extensive body of cardiovascular data on Vioxx, which was excluded from the authors, and analysis, which suggests Vioxx doesn't increase the risk of cardiovascular events..."*** ***"The researchers acknowledge that their analysis has 'several significant limitations."***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		"'We never saw any signal suggesting a cardiovascular problem,' said Geis. 'The theory put forward (by the article) about the effect of a specific COX-2 inhibitor on clot formation is just a theory, but there is no evidence to show that it is true. ***"Understanding the relationship warrants further studies with placebo, said Demopoulos. But Merck has created an extensive body of cardiovascular data on Vioxx, which was excluded front the authors, and analysis, which suggests Vioxx doesn't increase the risk of cardiovascular events, she added."*** ***"Until that data is collected, the article will have an effect on Vioxx and Celebrex use, said Hemant Shah, an analyst at HKS & Co."***
114	***The Wall Street Journal***, "Note of Caution: Study Raises Specter of Cardiovascular Risk For Hot Arthritis Pills—Vioxx	***"The marketers of the drugs and some outside experts dispute the conclusions."*** ***"Merck and Pharmacia say they believe no such clinical study is necessary. First, they say, no heart-attack risk emerged from***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
	and Celebrex Marketers Dispute the Research, Sought to Downplay It—A Spurned Appeal to JAMA," August 22, 2001	***their research. Moreover, they say research is already underway on Vioxx that should answer any remaining cardiac questions."*** ***Dr. Marvin Konstam, chief of cardiology at New England Medical Center, and a consultant to Merck stated, "there is no suggestion of a cardiovascular risk" from Vioxx.***
116	***Financial Times*** (FT.com), "Heart attack link to arthritis drugs," August 22, 2001	***"Merck's Vioxx and Pharmacia's Celebrex - which it co-markets with Pfizer - have become successful medicines for treating inflammation and are both expected to garner more than $3bn in sales this year.***
117	***Reuters News***, "UPDATE 1- Anti-arthritis drugmakers take hit after study," August 22, 2001	***"Merck... disagreed with the findings, saying patient experience and other data showed [Vioxx is] safe."***
118	***Los Angeles Times***, "Study Finds Health Risk in Popular Arthritis Medicines	***"The manufacturers of the two drugs disputed the study, arguing that it is poorly designed and that it doesn't include unpublished***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
	Vioxx, Celebrex, August 22, 2001	***results obtained from thousands of other patients."*** ***"When the drugs are compared directly to placebos, 'we find absolutely no difference in risk' for cardiovascular disease, said Laura Demopoulos of Merck & Co., which manufactures Vioxx."***
119	***The Plain Dealer*** Cleveland, OH, "Two arthritis drugs could heighten risk for heart patients," August 22, 2001	***"What we're really calling for is more trials that need to be done by the manufacturers of these drugs to get the answers that are vital in the interest of public health,"*** said Dr. Eric Topol. ***"But Laura Demopoulos, head of cardiovascular research for Merck ...[was]...noncommittal about the possibility of conducting additional studies. Demopoulos said the Clinic doctors overlooked data from 19 other studies showing that Vioxx did not increase the risk of heart attack."***
120	***St. Petersburg Times***, "'Super aspirin' alarm sounded," August 22, 2001	***"The analysis, which was strongly contested by the makers of the drugs, does not say they unquestionably increase cardiovascular risk. It says only that it's a possibility."***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		"Dr. Laura Demopoulos... noted that the Vioxx study involved patients with rheumatoid arthritis, a disease that raises the risk of heart trouble. She also said the results may reflect naproxen's potential heart friendly benefits rather than any negative effects from Vioxx."
121	***The Washington Post***, "You and A: Arthritis Drugs; Pain and Confusion," September 4, 2001	***"Merck spokeswoman Christine Fanelle said similarly that her company's studies of 28,000 patients suggested 'there is no increase in the risk of cardiovascular events as a result of treatment with Vioxx."***
122	***Bloomberg***, "Merck Misrepresents Safety of Vioxx, FDA Says in Warning Letter," September 24, 2001	***"'We continue to stand behind the overall safety and the cardiovascular safety of the product, but our immediate priority is to discuss our response' with the FDA, said Christine Fanelle, a Merck spokeswoman."***
123	***Reuters News***, "Merck Vioxx promotions said	***"Merck spokeswoman Christine Fanelle said the company was developing a response to the FDA that it planned to submit by***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
	misleading on safety," September 24, 2001	***Oct. 1. 'We continue to stand behind the overall safety and the cardiovascular safety of Vioxx.***
124	***USA Today***, "FDA sends a warning letter to maker of Vioxx painkiller," September 25, 2001	***"Merck spokeswoman Christine Fanelle says her company will not comment on the letter until after it files a response to the FDA, which has set a deadline for Oct. 1. "We continue to stand behind the overall safety and the cardiovascular safety of the product," Fanelle says.***
125	***Reuters News***, "Merck slips after FDA scolding on Vioxx safety claim," September 25, 2001	***"Merck may have no choice but to do another (safety) study,', UBS Warburg analyst Jeffrey Chaffkin said in a research report on Tuesday, following the FDA's warning letter to Merck. He said the clinical data on the cardiovascular safety of Vioxx 'are simply not definitive.'"*** ***"Merck spokeswoman Eve Slater on Tuesday said her company was still mulling whether to conduct a giant study to test the cardiovascular safety of the two-year-old Vioxx, which is expected to have global sales in 2001 of $3 billion."***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
126	***American Health Line***, "Vioxx: FDA Warns Merck About 'Misleading' Ads," September 25, 2001	***"In the meantime, Merck spokesperson Chris Fanelle said, 'We continue to stand by the overall and cardiovascular safety of the product."***
127	***The Associated Press***, "FDA says Merck misleading on Vioxx safety," September 25, 2001	***"The Company continues to stand behind the overall safety and cardiovascular safety of Vioxx," said Merck spokeswoman Jan Weiner.***
128	***The Wall Street Journal***, "FDA Warns Merck for Vioxx Promotions," September 25, 2001	***A Merck Spokesman, Greg Reaves, said "the company would have no comment on the specifics of the recent letter until it had responded first to the FDA." However, Mr. Reaves did say that, "We continue to stand behind the overall and cardiovascular safety profile of Vioxx."***
130	***Deseret News***, "18 Utahns sue pharmaceutical giant over Vioxx," Sept. 29, 2001	***"Merck has argued that Vioxx falsely look risky because naproxen...thins the blood much like aspirin does and thus protected against heart attacks. It aired that view in the recent promotions that state, 'Vioxx is a wonderful, effective' painkiller***

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		but not one that has a blood-thinning side benefit." ***"The company continues to stand behind the overall safety and cardiovascular safety of Vioxx," said Merck spokeswoman Jan Weiner.***
131	***Associated Press Newswires***, "Utah residents suing arthritis-drug maker," October 3, 2001	"Many critics say the findings are flawed because the Journal of the American Medical Association study was a compilation of earlier studies that didn't address the cardiovascular-risk questions surrounding Vioxx." ***"Merck has stood by the safety of the arthritis painkiller."***
132	***The New York Times***, "The Doctor's World: For Pain Reliever, Questions of Risk Remain Unresolved," October 9, 2001	***"In interviews, leading arthritis specialists who have no financial ties to Merck...or Pharmacia...say that they are not concerned and that they prescribe the drugs for patients who may have heart disease."*** "And so, while the company announced the heart attack findings to doctors and the public, it looked back at its data from studies using

Baron Exhibit #	Publication, Title, Date	Information Not Included in Baron Exh. 58
		different drugs or dummy pills in comparison to Vioxx. ***It found no evidence that Vioxx increased the risk of heart attacks,' Dr. Scolnick said."***

ADDITIONAL INFORMATION FROM "SAMPLE ANALYST REPORTS" (BARON DECL. EX. 59) NOT INCLUDED IN DEFENDANTS' COMPOSITE CHART

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
133	Salomon Smith Barney. Mar. 27, 2000. VIOXX GI Outcomes Trial-GI Safety Excellent, Side Effects Looming	"3M"	***No change***	"MRK announced the preliminary results from its landmark [VIGOR trial, which] is expected to garner FDA removal of the current NSAID GI warning on the Vioxx label: ***this label upgrade is expected to generate a new bolus of growth in the COX-2 market."***[1]

[1] Unless otherwise indicated, emphasis has been added.

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
134	JPMorgan Americas. Mar. 28, 2000. Pharmaceutical Industry: Merck's VIGOR Trial Confirms Vioxx's GI Safety	"Market Performer"	***No change***	***"Naproxen and other NSAIDS (most notably aspirin), block platelet aggregation thereby preventing clotting and the resultant risks of heart attacks and strokes. This is a COX -1 effect, not a COX-2 effect, therefore, none of the COX-2s should offer this cardiovascular benefit."***
135	JPMorgan Americas. Apr. 17, 2000. Industry: Celebrex Class Trial Confirms G.I. Safety (With a Slight Wrinkle) - No Cardiovascular Risk	"Market Perform"	***No change***	"[The increased CV events in VIGOR] may have been due to the anti-clotting benefits of NSAIDs and the fact that VIGOR did not allow background aspirin therapy." "In our view, the GI superiority of both Celebrex, and Vioxx is the primary issue and ***should be evident to the FDA. We expect***

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
				meaningful modification of the standard NSAID GI warning for both products after these data are approved."

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
136	Salomon Smith Barney. Apr. 24, 2000 MRK vs. PHA: COX-2 Inhibitor GI Outcomes Data at DDW May 20- 26	"3M"	***No change***	
137	Street Advisor. Apr. 28, 2000. Reiterating a hold on Merck	"Hold"	***No change***	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
138	Deutsche Banc Alex. Brown. May 1, 2000. Daily Research Highlights: Monday, May 1,2000	"Buy"	***No change***	***"We believe the market's reaction to this news is an overreaction, and expect that the release of the Vioxx data on May 24 will be a positive for the stock."***
139	Merrill Lynch. May 1, 2000. "Vioxx Speculation Seems Overdone," in Global Healthcare Bulletin.	"Accumulate"	***No change***	"Merck stock has reacted negatively to speculation concerning the company's arthritis drag Vioxx, ... [but there is] ***no reason to believe that Vioxx would cause a greater rate of cardiovascular events that would be seen without treatment***. It may be however that Naprosyn (which is known to inhibit platelet aggregation and thus blood clot formation) reduces the rate of cardiovascular events."

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
140	Goldman Sachs. May 2, 2000. US Pharma Focus	***"Recommended List" (Highest Rating)***	***No change***	**"We continue to believe that Vioxx is the better of the two products due to once-daily dosing and better efficacy and the Vioxx will eventually gain a leading market share."** **"Our favorite remains MRK, at a 5% discount to the S&P 500. We believe recent investor concerns about potential cardiovascular side-effects for Vioxx are unwarranted and that the stock has sold off to especially attractive levels. We expect MRK to have several positive events ahead of it to drive outperformance" (emphasis in original.)**

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
141	Pharma Market letter. May 8, 2000. Merck & Co. Falters on Vioxx Cardiovascular Events, Fules Competition with [*sic*]	No rating	N/A	"Merck said that, 'in response to speculative news reports.... [it confirms] the favorable cardiovascular profile of Vioxx.' The company went on to say that a review of data from completed and ongoing clinical trials, as well as post-marketing experience with the drug, show 'no difference in the incidence of cardiovascular events....among patients taking Vioxx, other NSAIDs and placebo.'" "Hemant Shah ... told Reuters that ***Vioxx probably does not increase the risk of cardiovascular events, but that the data showed naproxen's cardioprotective effects.***" ***"An FDA spokeswoman ... [added that the agency] 'continues to believe that Vioxx is effective and adequately safe for its labeled uses.'"***

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
142	JPMorgan Americas. May 24, 2000. Merck/Pharmacia: Merck Presents Vigor Trial at DDW	"Market Performer"	***No change***	"We believe that for both Vioxx and Celebrex, most physicians already believe that these drugs are safer than that the next level of marketing is to take that message directly to consumers. The extent to which the claim of safety superiority to NSAIDs can be made in DTC advertisements will be determined by what label modifications will be made by the FDA."
143	ABN-Amro. May 26, 2000. First Call	No rating	N/A	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
144	Arnhold and L. Bleichroeder. June 2, 2000. Cox-2 Inhibitor Update: Vioxx Cardiovascular Safety Issues Unresolved; GI Safety Trials Presented At Annual Digestive Disease Week Meeting	"Neutral"	***No change***	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
145	CSFB. Dec. 1, 2000. Equity Research - Pfizer, Inc.	No rating	NIA	"Merck's Vioxx has quickly captured share on the basis of a more convenient once-daily dosing regimen. Market share has moved into rough parity between the two agents, with expectations that Vioxx will move into a leading position in the category over the balance of 2000." ***"Right now the market appears to he giving Merck's Vioxx an inside advantage, with the drug gaining market share."***
146	Swedbank Markets. Jan. 11, 2001. Preview of FDA meeting on Celebrex	No rating	N/A	***"There is a risk of Vioxx continuing to notch up market share to some 55% of new prescriptions in the best of cases."***

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
147	JPMorgan Americas. Feb. 2, 2001. Pharmaceuticals Industry: Expect FDA COX-2 Label Changes	"Market Performer"	***No change***	***"We do not expect this to be problematic either, because of the generally accepted view that this finding is likely due to the anti- platelet benefits of the NSAID rather than any risk of Vioxx."***
148	Bear Stearns. Feb. 7, 2001. Cautious on MRK Shares Ahead of FDA Meeting on Vioxx Tomorrow	"Neutral"	***No change***	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
149	Bear Stearns. Feb. 8, 2001. Vioxx Label Change Meeting Update	Neutral	***No change***	"Merck's meeting today with an FDA Committee to discuss Vioxx label changes ***was better than expected*** given the concerns that arose out of Wednesday's FDA meeting for...Celebrex."
150	JPMorgan Americas. Feb. 8, 2001. Merck: A Rough Ride In Store For Vioxx After Celebrex Hammered	"Market Performer"	***No change***	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
151	SG Cowen. Feb. 9, 2001. Slight Positive For MRK As FDA Panel Recommends Changes To Vioxx Label	**"Strong Buy" (Highest Rating)**	***No change***	
152	CIBC World Markets. Feb. 9, 2001. Equity Research - A Weekly Dose of Pharmaceutical News	"Buy"	***No change***	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
153	Morgan Stanley Dean Witter. Feb. 14, 2001. US and the Americas Investment Perspectives	"Outperform"	***No change***	"[Morgan Stanley] had recommended Merck as the safer bet going into [the FDA Advisory Committee meetings]."

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
154	Lehman Brothers. Apr. 11, 2001. 'Approvable' Letter for Vioxx Safety Label Expansion	**"Strong Buy" (Highest Rating)**	***No change***	***"We feel that this likely label change supports our view that Vioxx will take a superior position to ... Celebrex."*** ***"We expect Vioxx to become the dominant COX-2 inhibitor on the market....We feel the label expansion for Vioxx, once approved, will cement the #1 position for Vioxx and cause this divergence to be maintained if not increased."*** ***"We want to reiterate our belief that this is strong positive for Vioxx and MRK. If the GI labeling comes to fruition, this will be the first significant labeling difference between Vioxx and Celebrex."***

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
155	Arnhold and L. Bleicharoeder. Apr. 27, 2001. COX-2 Inhibitor Outlook: Cardiovascular Safety Issues Raised in FDA Advisory Committee Meetings	"Neutral"	***No change***	"Merck identified a total of 321 patients who might have been benefited from low-dose aspirin. This post-hoc analysis ... [rendered] ... the differences seen in the incidence of heart attacks among patients not receiving aspirin ... no longer 'statistically significant' between Vioxx and naproxen. This tactic appeared to allay concerns that had emerged among investors, and possibly the medical community as well."

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
156	Dain Rauscher. May 22, 2001. Negative Story In New York Times On Merck's VIOXX	"Neutral"	***No change***	***"We believe that if there is a difference in the incidence of heart attack associated with the use of Vioxx vs. Naproxen, it relates to Naproxen having a[n] anti-platelet aggregation benefit that Vioxx doesn't have."*** "This information is NOT new news. We do NOT expect to see warning labels on Vioxx ... regarding the aforementioned issues." (emphasis in original.)
157	Tucker Anthony Sutra. June 22, 2001. Slightly Lowers EPS Guidance; Downgrading From Buy to	"Market Performer"	***Downgraded***	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
	Market Perform			
158	Goldman Sachs. June 25, 2001. MRK(RL): Lowering Guidance, Reiterate RL	**"Recommended List" (Highest Rating)**	***No change***	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
154	Morgan Stanley Dean Witter. June 25, 2001. Bounding the COX-2 Inhibitor Issue	"Outperform"	***No change***	***"Expected drivers of continued growth for Vioxx and Celebrex remain an expanding market and the ability to use recent studies (VIGOR, CLASS, SUCCESS) to build momentum behind the class' superior safety profile."***
160	CIBC World Markets. Aug. 22, 2001. Equity Research - JAMA Study Could Pressure Vioxx: Maintain Hold	"Hold"	***No change***	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
161	Deutsche Banc Alex. Brown. Aug. 22, 2001. JAMA Article Focuses on the Potential Increased Cardio Risks of COX-2's, Further Penetration of NSAID Market Limited	"Market Perform"	***No change***	***"This is not new news, and is unlikely, therefore, in our opinion, to reduce sales."***

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
162	CSFB. Aug. 22, 2001. JAMA COX-2 Study Possesses Considerable Limitations	***"Buy" (Highest Rating)***	***No change***	"[I response to the JAMA article suggesting increased CV risk with COX-2 drugs, Merck rebutted] that prior FDA review of its Vioxx product line ***confirmed overall safety***, with pending cardiovascular product labeling." "JAMA researchers themselves point out several significant limitations in their study." ***"The higher cardiac event profile in Merck's VIGOR clinical trial was largely associated with the exclusion of aspirin use in the trial as well as the well-understood cardio-protective qualities of naproxen used as the comparative molecule in the trial."***

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
163	Merrill Lynch. Sept. 24, 2001. Merck's Vioxx: FDA Vigilant on Cardiovascular Risks	"Neutral"	***No change***	
164	CIBC World Markets. Sept. 25, 2001. Equity Research - FDA Warning on Vioxx' Sparks Sell-off	"Hold"	***No change***	
165	CSFB. Sept. 25, 2001. Merck Receives Warning Letter from FDA on VIOXX	**"Buy" (Highest Rating)**	***No change***	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
166	Dain Rauscher. Sept. 25, 2001. FDA Warns Merck for Vioxx Marketing Practices	"Buy"	***No change***	
167	Lehman Brothers. Sept. 25, 2001. Spanked by DDMAC Over Vioxx Promotion	**"Strong Buy" (Highest Rating)**	***No change***	
168	UBS Warburg. Sept. 25, 2001. Research Note - FDA Warns Merck on Vioxx Marketing	"Buy"	***No change***	

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
169	SG Cowen. Oct. 2001. Pharmaceutical Therapeutic Categories Outlook	"2"	***No change***	"Vioxx...currently holds 51.1% share in the Coxib market, ***and this share appears sustainable.*** Vioxx's success appears attributable to its label advantages (once-daily dosage, pain claim) and Merck's widely respected marketing effort. The acute pain claim leads to a higher volume of short-use prescriptions." "Given the negative publicity [surrounding the COX-2 CV issue], we believe this issue is a near-term negative for the coxib class, but longer term, it appears manageable, ***given that the benefits of these drugs likely outweigh the very small risk***"

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
170	Morgan Stanley. Oct. 22, 2001. Not All Sales are Created Equal	"Outperform"	***No change***	"In the European Union, the Vioxx label was revised a couple of months ago. Though it's not appropriate to extrapolate the FDA's action, ***we were encouraged by the Eu regulators' relatively benign treatment of the cardiovascular data. Specifically, the European label states that Vioxx is not a substitute for aspirin for cardiovascular prophylaxis because of its lack of effect on platelets.***"
171	Deutsche Banc Alex. Brown. Nov. 29, 2001. MRK Responds to DDMAC Warning with Dear Doc Letter (Nov 19)- No Change to	"Market Perform"	***No change***	"Currently, Vioxx holds the edge in share of new Rxs at 50.1%, and Celebrex is maintaining its lead in the total rx category, at 51.7% share...It will be important to monitor prescriptions over the next several weeks, for the impact of the dear doctor letters."

Baron Exhibit #	Analyst	Rating	Rating Compared to Previous	Relevant Omitted Information
	Vioxx or EPS			
172	Deutsche Banc Alex. Brown. Jan. 22, 2002. Despite Weak Vioxx Sales, MRK "Makes the numbers"	"Market Perform"	***No change***	"We maintain our Market Perform rating, but expectations are low, and the shares appear attractive looking out over the longer term."

Merck & Co., Inc. (MRK)
Reported Daily Closing Stock Price
5/21/1999 through 10/29/2004

Date	Last Price
1999-05-21	67.4942
1999-05-24	66.1337
1999-05-25	64.5957
1999-05-26	63.7084
1999-05-27	62.4662
1999-05-28	64.0042
1999-06-01	64.4774
1999-06-02	63.1760
1999-06-03	64.6549
1999-06-04	66.8436
1999-06-07	65.6013
1999-06-08	64.9506
1999-06-09	66.1337
1999-06-10	64.2408
1999-06-11	62.9986
1999-06-14	62.7028
1999-06-15	64.0042
1999-06-16	64.9506
1999-06-17	65.7788
1999-06-18	65.3056
1999-06-21	65.7196
1999-06-22	66.0154
1999-06-23	64.2408
1999-06-24	65.2464
1999-06-25	65.1873
1999-06-28	66.3112
1999-06-29	67.6717
1999-06-30	69.6829
1999-07-01	71.2209

Date	Last Price
1999-07-02	71.2209
1999-07-06	69.9787
1999-07-07	70.6885
1999-07-08	71.2801
1999-07-09	71.1618
1999-07-12	70.9843
1999-07-13	70.6294
1999-07-14	68.8548
1999-07-15	69.0914
1999-07-16	67.3168
1999-07-19	66.8436
1999-07-20	65.0098
1999-07-21	65.0098
1999-07-22	65.6605
1999-07-23	65.3056
1999-07-26	64.6549
1999-07-27	65.0689
1999-07-28	64.8323
1999-07-29	63.1760
1999-07-30	64.0042
1999-08-02	63.7676
1999-08-03	63.4126
1999-08-04	61.0465
1999-08-05	60.5733
1999-08-06	58.9761
1999-08-09	58.7395
1999-08-10	58.9170
1999-08-11	57.6747
1999-08-12	58.6804
1999-08-13	60.3367
1999-08-16	61.3423
1999-08-17	61.5197

Date	Last Price
1999-08-18	61.3423
1999-08-19	61.9930
1999-08-20	64.0042
1999-08-23	66.3112
1999-08-24	65.3056
1999-08-25	66.7253
1999-08-26	65.1281
1999-08-27	64.4774
1999-08-30	64.4774
1999-08-31	63.5901
1999-09-01	65.1873
1999-09-02	64.5957
1999-09-03	66.7253
1999-09-07	65.1281
1999-09-08	65.4830
1999-09-09	65.4830
1999-09-10	66.0746
1999-09-13	65.8971
1999-09-14	64.8915
1999-09-15	64.4183
1999-09-16	65.7196
1999-09-17	65.0098
1999-09-20	66.3703
1999-09-21	65.0689
1999-09-22	66.1337
1999-09-23	64.8915
1999-09-24	62.5253
1999-09-27	62.4070
1999-09-28	61.8747
1999-09-29	60.8690
1999-09-30	61.3423
1999-10-01	64.4774

Date	Last Price
1999-10-04	65.5422
1999-10-05	66.3703
1999-10-06	68.2632
1999-10-07	67.0802
1999-10-08	69.8012
1999-10-11	71.1026
1999-10-12	69.9787
1999-10-13	68.6182
1999-10-14	69.0914
1999-10-15	66.4886
1999-10-18	68.3224
1999-10-19	70.9251
1999-10-20	71.6350
1999-10-21	74.4152
1999-10-22	75.4800
1999-10-25	74.3561
1999-10-26	73.4688
1999-10-27	73.6462
1999-10-28	75.1251
1999-10-29	75.3025
1999-11-01	75.3025
1999-11-02	73.8828
1999-11-03	74.8884
1999-11-04	75.4208
1999-11-05	76.0715
1999-11-08	74.7110
1999-11-09	73.8237
1999-11-10	73.4096
1999-11-11	72.6406
1999-11-12	71.8716
1999-11-15	71.1618
1999-11-16	71.9308

Date	Last Price
1999-11-17	73.1138
1999-11-18	74.4744
1999-11-19	75.1251
1999-11-22	74.5187
1999-11-23	74.0011
1999-11-24	75.4208
1999-11-26	75.5983
1999-11-29	75.7166
1999-11-30	74.4744
1999-12-01	72.2968
1999-12-02	71.3392
1999-12-03	73.2321
1999-12-06	71.6202
1999-12-07	69.2689
1999-12-08	69.3761
1999-12-09	67.3759
1999-12-10	67.6126
1999-12-13	64.5957
1999-12-14	65.9563
1999-12-15	67.8492
1999-12-16	65.7196
1999-12-17	62.9986
1999-12-20	63.0577
1999-12-21	62.5253
1999-12-22	63.5901
1999-12-23	66.0154
1999-12-27	66.7252
1999-12-28	66.0154
1999-12-29	64.5957
1999-12-30	64.1816
1999-12-31	63.5901
2000-01-03	64.0042

Date	Last Price
2000-01-04	61.7563
2000-01-05	64.1816
2000-01-06	64.7140
2000-01-07	70.9252
2000-01-10	68.8548
2000-01-11	69.0914
2000-01-12	70.4519
2000-01-13	70.7477
2000-01-14	70.1562
2000-01-18	67.0210
2000-01-19	67.6717
2000-01-20	69.0322
2000-01-21	68.5590
2000-01-24	66.4886
2000-01-25	67.0802
2000-01-26	68.9139
2000-01-27	70.1562
2000-01-28	72.2857
2000-01-31	74.4152
2000-02-01	72.6998
2000-02-02	72.7589
2000-02-03	72.1674
2000-02-04	71.0435
2000-02-07	71.2209
2000-02-08	71.3984
2000-02-09	67.5534
2000-02-10	65.3056
2000-02-11	61.7563
2000-02-14	62.5253
2000-02-15	62.1113
2000-02-16	61.9930
2000-02-17	59.8634

Date	Last Price
2000-02-18	58.6804
2000-02-22	61.9930
2000-02-23	59.7451
2000-02-24	58.6804
2000-02-25	56.9649
2000-02-28	58.2663
2000-02-29	58.2663
2000-03-01	56.7874
2000-03-02	56.0776
2000-03-03	54.4213
2000-03-06	53.4748
2000-03-07	51.0495
2000-03-08	53.7706
2000-03-09	57.8522
2000-03-10	56.3734
2000-03-13	53.9481
2000-03-14	53.4748
2000-03-15	56.6100
2000-03-16	61.5197
2000-03-17	59.3902
2000-03-20	58.3254
2000-03-21	60.5141
2000-03-22	60.9873
2000-03-23	59.5085
2000-03-24	58.4437
2000-03-27	57.8522
2000-03-28	58.2663
2000-03-29	60.5696
2000-03-30	60.6324
2000-03-31	58.7987
2000-04-03	63.1760
2000-04-04	64.0633

Date	Last Price
2000-04-05	64.5957
2000-04-06	62.0521
2000-04-07	61.9930
2000-04-10	62.8211
2000-04-11	63.7084
2000-04-12	61.4014
2000-04-13	62.2887
2000-04-14	60.1592
2000-04-17	60.9873
2000-04-18	62.7028
2000-04-19	65.3056
2000-04-20	66.0154
2000-04-24	68.0858
2000-04-25	68.6182
2000-04-26	68.0858
2000-04-27	67.6717
2000-04-28	65.7788
2000-05-01	63.9450
2000-05-02	65.5422
2000-05-03	64.6549
2000-05-04	63.5901
2000-05-05	65.5422
2000-05-08	66.1337
2000-05-09	65.2464
2000-05-10	64.3591
2000-05-11	64.5957
2000-05-12	64.4774
2000-05-15	65.8971
2000-05-16	67.1985
2000-05-17	66.0746
2000-05-18	66.1929
2000-05-19	68.5590

Date	Last Price
2000-05-22	68.4407
2000-05-23	69.8604
2000-05-24	70.6294
2000-05-25	70.6885
2000-05-26	70.5702
2000-05-30	70.9843
2000-05-31	70.6294
2000-06-01	68.5590
2000-06-02	65.2464
2000-06-05	65.4830
2000-06-06	65.8675
2000-06-07	66.7252
2000-06-08	65.6013
2000-06-09	66.1337
2000-06-12	66.1929
2000-06-13	69.5055
2000-06-14	69.0322
2000-06-15	68.9139
2000-06-16	67.1985
2000-06-19	68.2041
2000-06-20	67.0802
2000-06-21	68.5590
2000-06-22	67.4351
2000-06-23	68.7365
2000-06-26	70.2745
2000-06-27	70.2745
2000-06-28	70.0378
2000-06-29	70.1414
2000-06-30	72.5223
2000-07-03	72.3744
2000-07-05	73.0547
2000-07-06	71.3392

Date	Last Price
2000-07-07	70.3928
2000-07-10	70.8660
2000-07-11	70.6885
2000-07-12	69.4611
2000-07-13	65.4239
2000-07-14	63.6493
2000-07-17	63.7676
2000-07-18	62.8211
2000-07-19	61.7563
2000-07-20	60.6324
2000-07-21	60.3367
2000-07-24	65.8379
2000-07-25	67.1097
2000-07-26	66.2520
2000-07-27	68.4703
2000-07-28	68.8844
2000-07-31	67.8196
2000-08-01	70.1266
2000-08-02	70.9843
2000-08-03	71.1913
2000-08-04	69.8604
2000-08-07	69.1210
2000-08-08	68.4851
2000-08-09	66.7844
2000-08-10	67.6421
2000-08-11	68.5294
2000-08-14	68.9435
2000-08-15	69.3280
2000-08-16	69.6829
2000-08-17	69.9787
2000-08-18	68.1449
2000-08-21	68.0266

Date	Last Price
2000-08-22	68.6182
2000-08-23	68.3815
2000-08-24	68.6182
2000-08-25	69.0322
2000-08-28	68.5886
2000-08-29	67.3759
2000-08-30	67.3168
2000-08-31	66.1522
2000-09-01	65.4830
2000-09-05	63.5495
2000-09-06	62.4662
2000-09-07	63.6493
2000-09-08	63.9081
2000-09-11	64.2999
2000-09-12	64.0819
2000-09-13	64.6734
2000-09-14	63.9450
2000-09-15	63.5901
2000-09-18	63.5310
2000-09-19	64.6549
2000-09-20	64.2593
2000-09-21	66.3703
2000-09-22	69.2689
2000-09-25	68.3815
2000-09-26	66.4886
2000-09-27	68.9731
2000-09-28	69.2097
2000-09-29	70.4519
2000-10-02	70.0378
2000-10-03	69.6829
2000-10-04	69.6238
2000-10-05	71.1026

Date	Last Price
2000-10-06	71.9899
2000-10-09	71.2801
2000-10-10	72.7589
2000-10-11	72.4040
2000-10-12	73.0547
2000-10-13	72.1082
2000-10-16	72.7589
2000-10-17	74.0011
2000-10-18	74.0011
2000-10-19	73.4096
2000-10-20	77.4912
2000-10-23	80.2123
2000-10-24	80.8630
2000-10-25	82.6376
2000-10-26	82.0460
2000-10-27	83.2883
2000-10-30	83.9389
2000-10-31	85.1220
2000-11-01	84.9446
2000-11-02	84.3530
2000-11-03	83.1699
2000-11-06	85.1812
2000-11-07	82.2235
2000-11-08	85.9502
2000-11-09	85.5952
2000-11-10	86.6009
2000-11-13	84.5896
2000-11-14	86.1868
2000-11-15	86.7192
2000-11-16	85.3586
2000-11-17	83.7615
2000-11-20	85.5361

Date	Last Price
2000-11-21	87.0741
2000-11-22	85.8319
2000-11-24	84.6488
2000-11-27	86.7192
2000-11-28	87.6656
2000-11-29	89.7951
2000-11-30	87.7248
2000-12-01	85.7727
2000-12-04	87.0149
2000-12-05	85.1812
2000-12-06	84.7671
2000-12-07	86.1868
2000-12-08	84.7671
2000-12-11	85.7727
2000-12-12	86.4825
2000-12-13	87.0741
2000-12-14	86.1276
2000-12-15	85.5361
2000-12-18	84.5305
2000-12-19	86.6009
2000-12-20	88.3755
2000-12-21	87.5473
2000-12-22	85.6544
2000-12-26	87.7248
2000-12-27	87.7248
2000-12-28	89.6768
2000-12-29	88.6121
2001-01-02	88.0205
2001-01-03	84.3530
2001-01-04	80.4489
2001-01-05	78.8517
2001-01-08	79.0292

Date	Last Price
2001-01-09	79.5024
2001-01-10	78.7334
2001-01-11	77.2546
2001-01-12	77.0771
2001-01-16	78.8517
2001-01-17	76.8997
2001-01-18	78.4377
2001-01-19	78.0236
2001-01-22	77.9053
2001-01-23	75.3025
2001-01-24	74.7110
2001-01-25	77.4912
2001-01-26	77.8461
2001-01-29	76.0100
2001-01-30	76.6630
2001-01-31	77.7799
2001-02-01	79.9567
2001-02-02	79.4740
2001-02-05	79.9567
2001-02-06	79.8431
2001-02-07	77.4675
2001-02-08	78.5276
2001-02-09	78.2910
2001-02-12	78.5370
2001-02-13	76.4264
2001-02-14	75.3664
2001-02-15	73.9183
2001-02-16	73.1517
2001-02-20	73.7290
2001-02-21	74.4957
2001-02-22	73.5397
2001-02-23	72.9529

Date	Last Price
2001-02-26	75.0825
2001-02-27	75.6314
2001-02-28	75.9059
2001-03-01	75.4800
2001-03-02	75.8586
2001-03-05	75.2718
2001-03-06	73.3031
2001-03-07	70.4164
2001-03-08	70.7855
2001-03-09	71.6374
2001-03-12	70.1798
2001-03-13	69.0251
2001-03-14	68.0787
2001-03-15	70.0852
2001-03-16	67.6244
2001-03-19	68.2112
2001-03-20	66.4886
2001-03-21	64.3212
2001-03-22	65.9775
2001-03-23	65.2866
2001-03-26	67.6528
2001-03-27	69.6687
2001-03-28	71.1263
2001-03-29	70.2271
2001-03-30	71.8361
2001-04-02	70.2745
2001-04-03	68.9116
2001-04-04	70.4921
2001-04-05	71.7225
2001-04-06	72.3283
2001-04-09	73.8237
2001-04-10	74.1928

Date	Last Price
2001-04-11	73.0192
2001-04-12	75.2434
2001-04-16	74.8648
2001-04-17	76.5211
2001-04-18	75.0541
2001-04-19	74.0792
2001-04-20	69.6687
2001-04-23	70.2745
2001-04-24	69.5268
2001-04-25	70.8518
2001-04-26	70.8423
2001-04-27	71.5995
2001-04-30	71.9024
2001-05-01	71.5522
2001-05-02	70.8991
2001-05-03	71.2398
2001-05-04	72.2810
2001-05-07	72.7826
2001-05-08	72.3472
2001-05-09	73.1801
2001-05-10	72.4229
2001-05-11	71.8740
2001-05-14	72.5838
2001-05-15	71.8361
2001-05-16	73.9183
2001-05-17	74.3916
2001-05-18	73.2558
2001-05-21	73.2558
2001-05-22	71.0790
2001-05-23	70.0378
2001-05-24	68.6182
2001-05-25	68.7128

Date	Last Price
2001-05-29	70.4070
2001-05-30	69.3564
2001-05-31	69.0819
2001-06-01	70.2271
2001-06-04	70.3407
2001-06-05	71.2966
2001-06-06	69.9905
2001-06-07	70.8045
2001-06-08	70.2461
2001-06-11	68.3815
2001-06-12	68.7223
2001-06-13	69.2144
2001-06-14	69.9432
2001-06-15	69.8012
2001-06-18	70.2745
2001-06-19	70.6057
2001-06-20	70.6625
2001-06-21	70.4827
2001-06-22	64.1698
2001-06-25	63.8859
2001-06-26	62.6744
2001-06-27	62.1255
2001-06-28	61.5197
2001-06-29	60.4881
2001-07-02	60.9045
2001-07-03	61.2358
2001-07-05	60.7058
2001-07-06	60.0433
2001-07-09	61.1411
2001-07-10	60.3083
2001-07-11	59.0211
2001-07-12	57.7339

Date	Last Price
2001-07-13	58.2071
2001-07-16	59.6079
2001-07-17	61.0276
2001-07-18	63.9332
2001-07-19	63.6966
2001-07-20	62.8732
2001-07-23	62.1823
2001-07-24	61.4535
2001-07-25	61.5103
2001-07-26	61.2926
2001-07-27	61.6522
2001-07-30	62.7028
2001-07-31	64.3402
2001-08-01	64.3496
2001-08-02	64.1603
2001-08-03	64.4632
2001-08-06	63.8102
2001-08-07	64.8134
2001-08-08	64.2171
2001-08-09	64.1887
2001-08-10	65.3340
2001-08-13	65.9208
2001-08-14	66.2520
2001-08-15	65.2109
2001-08-16	66.2426
2001-08-17	65.4475
2001-08-20	66.8010
2001-08-21	66.9619
2001-08-22	67.4067
2001-08-23	64.8418
2001-08-24	65.3245
2001-08-27	65.0216

Date	Last Price
2001-08-28	64.3686
2001-08-29	63.5451
2001-08-30	62.4567
2001-08-31	61.6144
2001-09-04	61.8037
2001-09-05	64.0752
2001-09-06	62.2296
2001-09-07	60.8572
2001-09-10	62.5608
2001-09-17	63.5546
2001-09-18	64.6525
2001-09-19	64.2266
2001-09-20	63.2707
2001-09-21	62.1823
2001-09-24	60.5638
2001-09-25	59.1063
2001-09-26	59.9581
2001-09-27	62.6649
2001-09-28	63.0341
2001-10-01	64.6620
2001-10-02	64.7755
2001-10-03	64.0373
2001-10-04	63.5073
2001-10-05	64.6052
2001-10-08	64.9270
2001-10-09	64.2929
2001-10-10	64.8229
2001-10-11	64.5295
2001-10-12	65.4570
2001-10-15	66.2047
2001-10-16	65.5990
2001-10-17	65.3529

Date	Last Price
2001-10-18	62.7501
2001-10-19	61.8794
2001-10-22	63.6587
2001-10-23	63.3653
2001-10-24	63.4126
2001-10-25	62.9300
2001-10-26	62.2769
2001-10-29	61.7374
2001-10-30	61.2831
2001-10-31	60.3934
2001-11-01	60.7626
2001-11-02	61.5481
2001-11-05	61.8794
2001-11-06	61.9362
2001-11-07	61.2737
2001-11-08	61.7280
2001-11-09	61.1506
2001-11-12	60.9329
2001-11-13	61.1222
2001-11-14	61.4156
2001-11-15	61.1979
2001-11-16	61.4251
2001-11-19	61.1317
2001-11-20	60.7058
2001-11-21	62.0687
2001-11-23	62.3999
2001-11-26	63.4600
2001-11-27	63.0246
2001-11-28	61.8510
2001-11-29	63.2707
2001-11-30	64.1225
2001-12-03	64.8323

Date	Last Price
2001-12-04	64.0089
2001-12-05	62.6933
2001-12-06	62.6082
2001-12-07	63.4126
2001-12-10	63.4032
2001-12-11	57.4500
2001-12-12	55.3867
2001-12-13	54.8377
2001-12-14	54.9797
2001-12-17	54.1090
2001-12-18	55.3678
2001-12-19	56.1533
2001-12-20	56.5508
2001-12-21	56.4373
2001-12-24	56.8158
2001-12-26	56.7401
2001-12-27	56.5792
2001-12-28	56.3331
2001-12-31	55.6517
2002-01-02	56.5603
2002-01-03	55.8694
2002-01-04	55.7369
2002-01-07	54.9892
2002-01-08	55.5854
2002-01-09	55.6706
2002-01-10	55.8126
2002-01-11	55.8221
2002-01-14	55.6990
2002-01-15	55.5097
2002-01-16	55.1122
2002-01-17	55.4624
2002-01-18	54.8945

Date	Last Price
2002-01-22	56.1155
2002-01-23	55.1311
2002-01-24	54.5349
2002-01-25	53.9102
2002-01-28	53.9481
2002-01-29	54.4402
2002-01-30	55.6896
2002-01-31	56.0113
2002-02-01	56.2480
2002-02-04	55.3110
2002-02-05	56.2196
2002-02-06	55.4813
2002-02-07	55.2069
2002-02-08	55.9830
2002-02-11	56.2669
2002-02-12	56.9957
2002-02-13	57.3364
2002-02-14	56.4940
2002-02-15	56.6076
2002-02-19	56.0776
2002-02-20	57.9800
2002-02-21	57.7434
2002-02-22	58.2071
2002-02-25	57.5825
2002-02-26	57.4026
2002-02-27	57.6203
2002-02-28	58.0462
2002-03-01	59.6079
2002-03-04	59.6363
2002-03-05	58.5005
2002-03-06	59.3145
2002-03-07	59.7877

Date	Last Price
2002-03-08	59.1536
2002-03-11	59.3807
2002-03-12	60.0906
2002-03-13	60.9235
2002-03-14	60.0433
2002-03-15	56.5508
2002-03-18	55.6422
2002-03-19	55.2920
2002-03-20	54.9702
2002-03-21	54.9419
2002-03-22	55.0838
2002-03-25	54.4308
2002-03-26	54.3267
2002-03-27	54.3361
2002-03-28	54.4970
2002-04-01	54.5159
2002-04-02	54.3645
2002-04-03	54.2225
2002-04-04	52.8123
2002-04-05	52.2918
2002-04-08	51.2601
2002-04-09	50.7207
2002-04-10	50.2947
2002-04-11	49.3578
2002-04-12	51.1087
2002-04-15	51.6103
2002-04-16	52.0741
2002-04-17	52.1025
2002-04-18	53.5411
2002-04-19	53.8913
2002-04-22	53.4938
2002-04-23	52.5189

Date	Last Price
2002-04-24	51.9037
2002-04-25	51.9510
2002-04-26	51.5535
2002-04-29	51.7428
2002-04-30	51.4305
2002-05-01	52.3391
2002-05-02	52.5946
2002-05-03	52.5284
2002-05-06	52.8786
2002-05-07	52.5757
2002-05-08	53.5979
2002-05-09	52.7745
2002-05-10	52.6325
2002-05-13	53.6073
2002-05-14	54.4213
2002-05-15	53.8534
2002-05-16	53.5695
2002-05-17	55.0176
2002-05-20	55.0838
2002-05-21	54.7052
2002-05-22	54.4402
2002-05-23	54.4213
2002-05-24	53.4654
2002-05-28	53.0395
2002-05-29	54.0711
2002-05-30	53.3707
2002-05-31	54.0427
2002-06-03	52.2634
2002-06-04	51.7239
2002-06-05	52.0078
2002 06 06	50.3515
2002-06-07	49.8594

Date	Last Price
2002-06-10	51.3926
2002-06-11	49.1022
2002-06-12	49.2063
2002-06-13	49.2442
2002-06-14	49.6985
2002-06-17	50.5124
2002-06-18	50.1244
2002-06-19	49.7269
2002-06-20	49.4051
2002-06-21	47.3039
2002-06-24	46.8496
2002-06-25	46.4237
2002-06-26	47.6352
2002-06-27	48.1558
2002-06-28	47.9286
2002-07-01	46.1398
2002-07-02	44.4078
2002-07-03	44.7485
2002-07-05	46.2439
2002-07-08	45.2501
2002-07-09	43.3004
2002-07-10	41.2371
2002-07-11	41.9091
2002-07-12	43.1111
2002-07-15	43.2531
2002-07-16	41.6536
2002-07-17	42.1174
2002-07-18	39.7512
2002-07-19	39.2780
2002-07-22	37.8678
2002-07-23	36.9592
2002-07-24	40.3191

Date	Last Price
2002-07-25	42.0795
2002-07-26	43.5370
2002-07-29	45.8653
2002-07-30	45.9126
2002-07-31	46.9443
2002-08-01	45.3826
2002-08-02	45.2975
2002-08-05	43.1017
2002-08-06	44.3226
2002-08-07	46.3291
2002-08-08	47.6541
2002-08-09	48.2883
2002-08-12	48.5059
2002-08-13	47.0200
2002-08-14	48.3545
2002-08-15	47.8718
2002-08-16	47.3229
2002-08-19	48.5154
2002-08-20	47.9286
2002-08-21	49.1022
2002-08-22	50.9194
2002-08-23	49.7458
2002-08-26	49.8499
2002-08-27	48.8940
2002-08-28	47.9286
2002-08-29	48.0232
2002-08-30	47.8150
2002-09-03	45.3069
2002-09-04	46.4995
2002-09-05	45.7139
2002-09-06	45.9978
2002-09-09	46.7550

Date	Last Price
2002-09-10	46.9821
2002-09-11	46.9159
2002-09-12	46.4711
2002-09-13	46.6320
2002-09-16	46.1966
2002-09-17	44.8053
2002-09-18	44.5403
2002-09-19	42.7704
2002-09-20	43.2910
2002-09-23	42.8272
2002-09-24	43.4424
2002-09-25	45.1460
2002-09-26	46.1398
2002-09-27	43.7831
2002-09-30	43.2626
2002-10-01	43.8967
2002-10-02	44.4362
2002-10-03	43.8115
2002-10-04	41.8902
2002-10-07	41.7672
2002-10-08	43.5370
2002-10-09	43.1869
2002-10-10	43.5465
2002-10-11	44.7674
2002-10-14	46.9443
2002-10-15	48.1558
2002-10-16	47.2282
2002-10-17	48.0327
2002-10-18	48.2977
2002-10-21	48.4113
2002-10-22	47.9381
2002-10-23	48.6101

Date	Last Price
2002-10-24	47.7866
2002-10-25	50.0771
2002-10-28	51.3264
2002-10-29	50.5881
2002-10-30	51.3358
2002-10-31	51.3358
2002-11-01	51.1655
2002-11-04	50.8058
2002-11-05	51.2980
2002-11-06	53.0016
2002-11-07	52.4527
2002-11-08	52.9259
2002-11-11	52.0836
2002-11-12	51.8848
2002-11-13	49.9729
2002-11-14	51.0519
2002-11-15	52.4053
2002-11-18	53.5316
2002-11-19	54.5254
2002-11-20	54.4024
2002-11-21	55.6706
2002-11-22	55.8694
2002-11-25	57.0808
2002-11-26	55.4813
2002-11-27	56.6928
2002-11-29	56.2290
2002-12-02	56.7401
2002-12-03	55.6706
2002-12-04	55.6896
2002-12-05	56.0587
2002-12-06	55.4340
2002-12-09	55.6044

Date	Last Price
2002-12-10	55.8410
2002-12-11	55.2636
2002-12-12	54.0995
2002-12-13	54.2699
2002-12-16	55.3678
2002-12-17	55.1785
2002-12-18	53.8156
2002-12-19	53.2666
2002-12-20	53.3423
2002-12-23	53.6168
2002-12-24	53.8818
2002-12-26	53.8913
2002-12-27	53.0016
2002-12-30	53.7682
2002-12-31	53.5790
2003-01-02	55.1311
2003-01-03	55.8315
2003-01-06	56.6739
2003-01-07	55.9451
2003-01-08	55.8221
2003-01-09	56.5792
2003-01-10	56.6076
2003-01-13	56.5982
2003-01-14	56.6076
2003-01-15	56.1155
2003-01-16	55.6990
2003-01-17	55.2163
2003-01-21	53.6831
2003-01-22	52.6420
2003-01-23	52.3864
2003-01-24	50.6828
2003-01-27	48.9886

Date	Last Price
2003-01-28	51.4873
2003-01-29	52.4243
2003-01-30	51.5914
2003-01-31	52.4243
2003-02-03	52.8691
2003-02-04	51.9132
2003-02-05	51.7334
2003-02-06	51.4967
2003-02-07	50.6923
2003-02-10	51.4873
2003-02-11	51.1182
2003-02-12	50.4935
2003-02-13	49.7837
2003-02-14	51.0235
2003-02-18	51.9605
2003-02-19	51.4494
2003-02-20	50.5219
2003-02-21	50.9289
2003-02-24	49.6512
2003-02-25	49.9256
2003-02-26	49.3104
2003-02-27	49.9730
2003-02-28	49.9256
2003-03-03	49.6795
2003-03-04	48.8467
2003-03-05	49.0927
2003-03-06	49.1685
2003-03-07	49.5565
2003-03-10	48.4492
2003-03-11	48.0516
2003-03-12	48.5154
2003-03-13	48.3734

Date	Last Price
2003-03-14	48.0800
2003-03-17	49.4051
2003-03-18	50.1812
2003-03-19	51.5441
2003-03-20	52.0457
2003-03-21	53.4748
2003-03-24	51.7239
2003-03-25	52.5284
2003-03-26	51.5535
2003-03-27	52.1214
2003-03-28	52.3864
2003-03-31	51.8469
2003-04-01	52.6230
2003-04-02	53.7304
2003-04-03	53.1057
2003-04-04	54.1374
2003-04-07	53.7872
2003-04-08	53.6736
2003-04-09	52.6704
2003-04-10	52.7271
2003-04-11	52.4527
2003-04-14	53.6357
2003-04-15	53.8818
2003-04-16	53.1057
2003-04-17	52.8975
2003-04-21	53.9102
2003-04-22	55.7369
2003-04-23	55.0270
2003-04-24	55.1785
2003-04-25	53.7115
2003-04-28	54.1374
2003-04-29	54.2888

Date	Last Price
2003-04-30	55.0649
2003-05-01	55.3678
2003-05-02	56.1155
2003-05-05	55.8031
2003-05-06	55.7463
2003-05-07	55.4151
2003-05-08	55.0838
2003-05-09	55.1122
2003-05-12	55.8410
2003-05-13	56.1533
2003-05-14	56.4278
2003-05-15	56.3426
2003-05-16	56.2669
2003-05-19	53.6168
2003-05-20	52.0457
2003-05-21	52.4148
2003-05-22	52.5757
2003-05-23	52.4811
2003-05-27	53.3234
2003-05-28	52.7555
2003-05-29	51.8280
2003-05-30	52.6041
2003-06-02	52.7461
2003-06-03	53.2856
2003-06-04	53.8061
2003-06-05	55.6044
2003-06-06	55.8978
2003-06-09	55.1785
2003-06-10	55.3204
2003-06-11	56.1533
2003-06-12	56.1249
2003-06-13	56.0587

Date	Last Price
2003-06-16	57.5446
2003-06-17	59.0305
2003-06-18	59.8540
2003-06-19	58.9643
2003-06-20	59.5227
2003-06-23	58.7845
2003-06-24	58.8223
2003-06-25	57.9043
2003-06-26	58.6804
2003-06-27	57.7528
2003-06-30	57.3080
2003-07-01	58.1787
2003-07-02	58.4154
2003-07-03	57.8664
2003-07-07	58.5762
2003-07-08	58.3586
2003-07-09	58.0936
2003-07-10	57.7718
2003-07-11	58.1503
2003-07-14	58.4437
2003-07-15	58.5573
2003-07-16	58.4248
2003-07-17	57.7434
2003-07-18	58.4627
2003-07-21	56.6171
2003-07-22	54.7147
2003-07-23	54.7904
2003-07-24	53.9386
2003-07-25	54.4402
2003-07-28	53.6263
2003-07-29	52.4243
2003-07-30	52.4905

Date	Last Price
2003-07-31	52.3202
2003-08-01	51.3169
2003-08-04	51.2317
2003-08-05	50.6449
2003-08-06	51.3169
2003-08-07	52.9070
2003-08-08	52.6136
2003-08-11	52.0930
2003-08-12	51.6103
2003-08-13	50.5598
2003-08-14	50.4840
2003-08-15	50.6165
2003-08-18	50.6260
2003-08-19	50.8437
2003-08-20	52.1200
2003-08-21	51.3200
2003-08-22	50.2700
2003-08-25	50.2900
2003-08-26	50.3000
2003-08-27	50.3000
2003-08-28	49.7600
2003-08-29	50.3200
2003-09-02	51.0700
2003-09-03	50.6800
2003-09-04	50.6000
2003-09-05	51.0000
2003-09-08	52.6000
2003-09-09	52.7900
2003-09-10	53.7000
2003-09-11	53.3000
2003-09-12	53.5000
2003-09-15	53.0900

Date	Last Price
2003-09-16	53.7900
2003-09-17	53.2100
2003-09-18	53.0800
2003-09-19	52.2900
2003-09-22	51.3900
2003-09-23	51.2100
2003-09-24	50.6500
2003-09-25	50.3700
2003-09-26	50.8300
2003-09-29	51.0000
2003-09-30	50.6200
2003-10-01	51.1600
2003-10-02	51.0000
2003-10-03	50.1100
2003-10-06	50.2300
2003-10-07	50.1000
2003-10-08	49.9800
2003-10-09	48.9900
2003-10-10	49.4800
2003-10-13	49.7100
2003-10-14	49.7000
2003-10-15	48.8900
2003-10-16	49.0900
2003-10-17	48.6300
2003-10-20	48.3600
2003-10-21	48.9100
2003-10-22	45.7200
2003-10-23	45.5000
2003-10-24	44.7900
2003-10-27	44.8800
2003-10-28	44.9200
2003-10-29	44.9200

Date	Last Price
2003-10-30	43.9400
2003-10-31	44.2500
2003-11-03	44.6900
2003-11-04	43.7900
2003-11-05	43.4000
2003-11-06	43.6000
2003-11-07	43.9300
2003-11-10	43.4000
2003-11-11	43.8700
2003-11-12	44.2500
2003-11-13	45.8000
2003-11-14	46.5800
2003-11-17	46.0800
2003-11-18	46.1500
2003-11-19	46.1500
2003-11-20	45.1600
2003-11-21	42.2100
2003-11-24	42.0900
2003-11-25	41.4200
2003-11-26	41.0200
2003-11-28	40.6000
2003-12-01	42.0800
2003-12-02	42.5000
2003-12-03	43.6300
2003-12-04	43.2900
2003-12-05	43.0700
2003-12-08	43.5800
2003-12-09	43.5600
2003-12-10	43.1500
2003-12-11	43.6000
2003-12-12	43.6500
2003-12-15	43.7000

Date	Last Price
2003-12-16	44.1300
2003-12-17	44.1000
2003-12-18	44.6000
2003-12-19	44.3600
2003-12-22	44.2100
2003-12-23	44.7700
2003-12-24	44.9400
2003-12-26	45.1000
2003-12-29	45.6900
2003-12-30	45.5000
2003-12-31	46.2000
2004-01-02	47.0500
2004-01-05	48.0000
2004-01-06	47.7700
2004-01-07	47.8300
2004-01-08	48.0800
2004-01-09	47.1300
2004-01-12	45.9000
2004-01-13	45.6700
2004-01-14	46.2900
2004-01-15	45.9300
2004-01-16	46.1900
2004-01-20	45.9800
2004-01-21	46.2500
2004-01-22	46.1100
2004-01-23	45.7800
2004-01-26	47.2000
2004-01-27	47.3600
2004-01-28	47.9000
2004-01-29	48.2800
2004-01-30	47.6000
2004-02-02	48.0700

Date	Last Price
2004-02-03	48.5000
2004-02-04	48.9400
2004-02-05	48.7400
2004-02-06	48.7600
2004-02-09	48.1700
2004-02-10	48.4000
2004-02-11	48.6200
2004-02-12	48.3100
2004-02-13	48.8800
2004-02-17	48.8600
2004-02-18	49.0800
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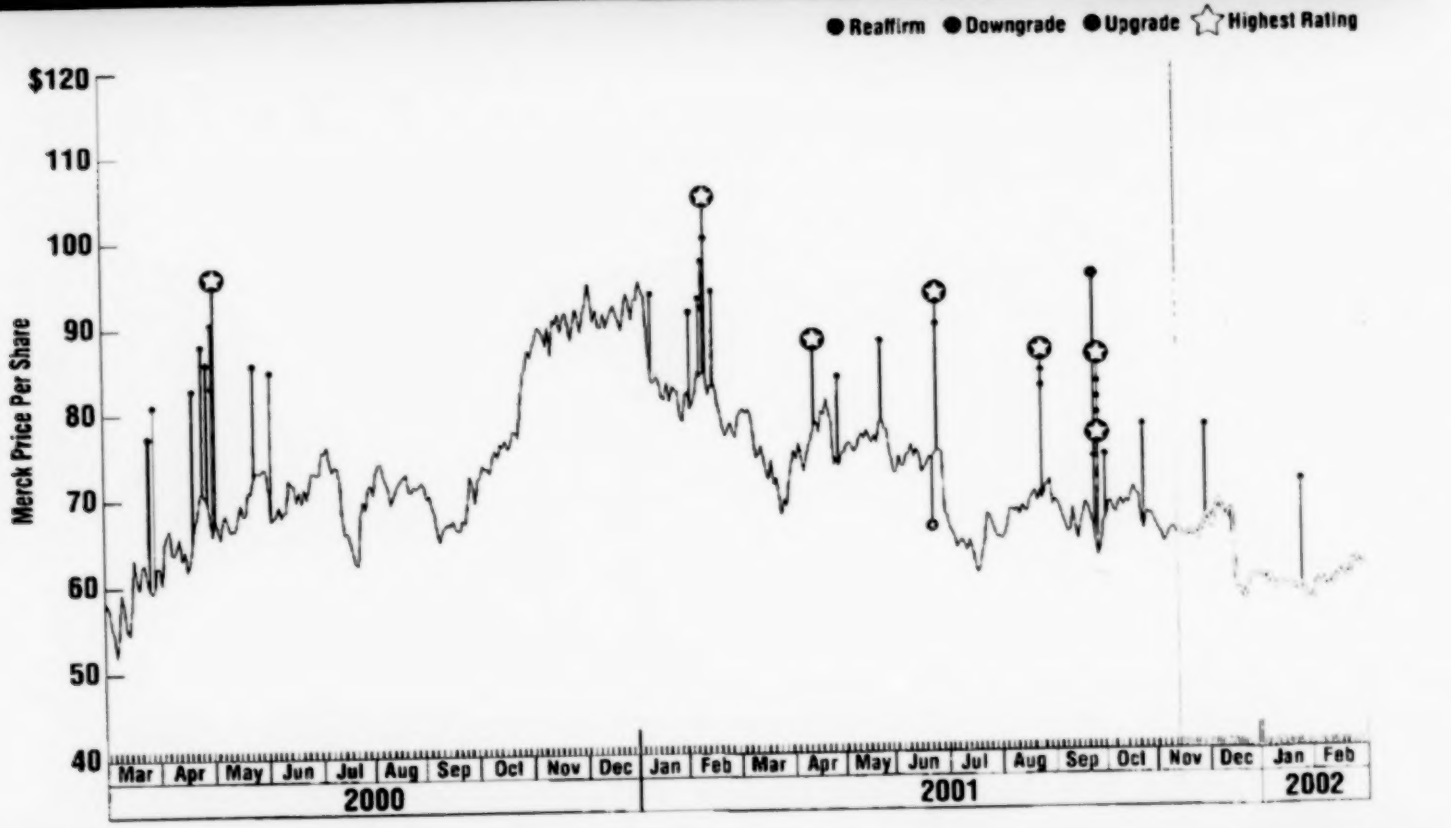
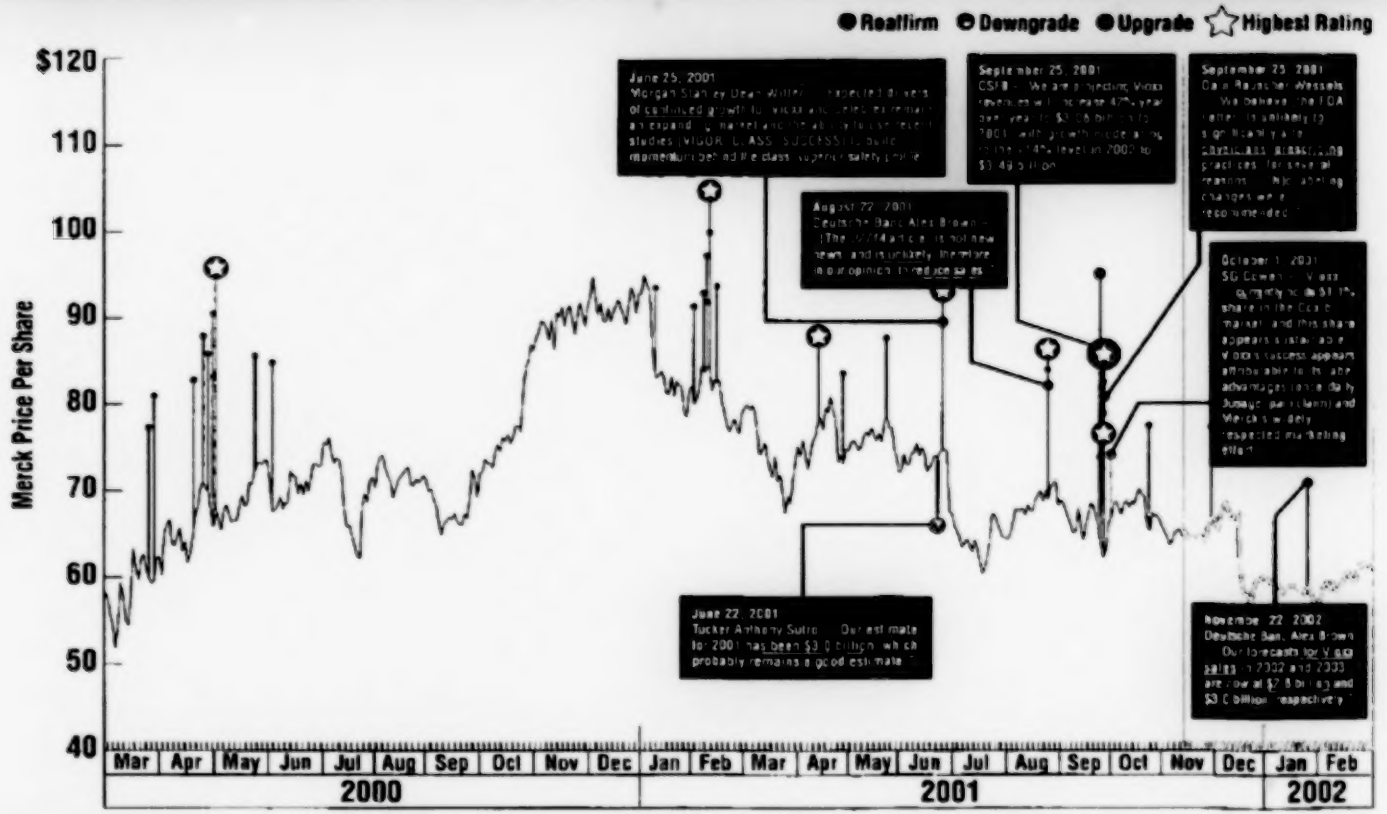
Analyst Reports Cited by the Parties



Analyst Reports Cited by the Parties



Merck Historical Stock Price: March 1999 – January 2005

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MERCK & CO INC

Filing Type:	**10-Q**
Description:	**N/A**
Filing Date:	**09/30/03**
Ticker:	**MRK**
Cusip:	**589331**
State:	**NJ**
Country:	**US**
Primary SIC:	**2834**
Primary Exchange:	**NYS**
Billing Cross Reference:	
Date Printed:	**03/15/06**

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	($ in millions)	
	September 30 2003	December 31 2002
Customer relationships – Medco Health	--	$3,172.2
Patents and product rights	1,530.7	1,355.2
Other	153.7	121.5
Total acquired cost	$ 1,784.4	$ 4,648.9
Customer relationships – Medco Health	--	$ 757.3
Patents and product rights	821.0	694.4
Other	93.7	83.2
Total accumulated amortization	$ 914.7	$ 1,534.9

7. In August 2003, the Company entered into a ten-year $500.0 million notional amount pay-floating, receive-fixed interest rate swap contract designated as a hedge of the fair value changes in $500.0 million of ten-year fixed rate notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The swap effectively converts fixed rate obligations to floating rate instruments. The fair value changes in the notes are fully offset in Interest expense by the fair value changes in the swap contract.

8. The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual

property and commercial litigation, as well as additional matters such as antitrust actions.

As previously reported, the Company is party to a number of antitrust suits, certain of which have been certified as class actions, instituted by most of the nation's retail pharmacies and consumers in several states, alleging conspiracies in restraint of trade and challenging the pricing and/or purchasing practices of the Company. A significant number of other pharmaceutical companies and wholesalers have also been sued in the same or similar litigation. In 1996, the Company and several other defendants finalized an agreement to settle the federal class action alleging conspiracy, which represents the single largest group of retail pharmacy claims. Since that time, the Company has entered into other settlements on satisfactory terms. The Company has not engaged in any conspiracy and no admission of wrongdoing was made nor was included in any settlement agreements. While it is not feasible to predict the final outcome of the remaining proceedings, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the Company's financial position, results of operations or liquidity.

As previously reported, a number of lawsuits, involving individual claims as well as putative class actions, have been filed against the Company with respect to "Vioxx".

Certain of the lawsuits include allegations regarding gastrointestinal bleeding, cardiovascular events, and kidney damage. The lawsuits have been filed in federal courts as well as in a number of state courts. While cases in other jurisdictions are proceeding separately, the actions filed in the state courts of California and New Jersey have been transferred to a single judge in each state for coordinated proceedings. The Company anticipates that one or more of the lawsuits in various jurisdictions may go to trial in the first half of 2004. Litigation is inherently subject to uncertainties and no assurance can be given on the outcome of any given trial. However, the Company believes that these lawsuits are without merit, and will vigorously defend against them.

As previously disclosed, the Company is a party in claims brought under the Consumer Protection Act of 1987 in the United Kingdom which allege that certain children suffer from a variety of conditions as a result of being vaccinated with various bivalent vaccines for measles and rubella and/or trivalent vaccines for measles, mumps and rubella, including the Company's M-M-R II. In connection with those claims, eight lead cases had been selected for a trial scheduled to commence in April 2004: two against the Company, and six against other pharmaceutical companies. The trial of the eight cases was initially to be limited to issues of causation and defect on the conditions of autistic spectrum disorders, with or without inflammatory bowel disease. In early September 2003, the Legal Services Commission announced its decision to withdraw public funding of the litigation brought by the claimants. This decision was confirmed on appeal by the Funding Review Committee on September 30, 2003. The April 2004 trial date has been vacated and the claims stayed pending the outcome of any application for judicial review of the funding

withdrawal decision. The Company believes tha the lawsuits are without merit and will vigorously defend against them.

As previously reported, the Company is a party to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites and takes an active role in identifying and providing for these costs. In management's opinion, the liabilities for all environmental matters which are probable and reasonably estimable have been accrued and totaled $166.2 million at September 30, 2003. These liabilitites are undiscounted, do not consider potential recoveries from insurers or other parties and will be paid out over the periods of remediation for the applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonablly possible expenditures that may be incurred in excess of the liabilities accrued should exceed $100.0 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

As previously disclosed, on July 31, 2003, a shareholder derivative complaint in federal court in the District of New Jersey, which was originally filed in May 2003, was amended to add Arthur Andersen LLP as a defendant and to add certain new allegations. The lawsuit is based on previously-disclosed allegations relating to the

Company's revenue recognition practices for retail co-payments and further alleges that certain individual defendants breached their fiduciary duty by failing to prevent the conduct at issue in the previously-disclosed Gruer cases, the antitrust claims pending in the Northern District of Illinois, and the qui tam actions in which the U.S. Attorney's office for the Eastern District of Pennsylvania has intervened against Medco Health. The complaint seeks monetary damages from those Merck directors who are defendants in the lawsuit in an unspecified amount as well as injunctive and other relief.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Case No. CV-01-3441
Filed May 29, 2001

DOMINICK LETTIERI AND MARY LOMBARDOZZI,
PLAINTIFFS
v.
MERCK & CO., INC., PHARMACIA CORP. AND PFIZER INC.,
DEFENDANTS

CIVIL ACTION COMPLAINT
JURY TRIAL DEMANDED

Plaintiffs for their complaint allege upon actual knowledge as to their acts and status and upon information and belief as to all other matters.

SUMMARY OF CLAIMS

1. This class action proceeding is brought on behalf of a nationwide class of persons who are taking the osteoarthritis drug refecoxib marketed by defendant Merck & Co. Inc. ("Merck") under the brand names "Vioxx;" and a similar drug celecoxib marketed by defendants Pharmacia Corporate ("Pharmacia") and Pfizer Inc. ("Pfizer") under the brand name "Celebrex" for the treatment of osteoarthris and/or for persons who have taken such drugs for osteoarthris during the relevant time. Both of these drugs belong to a class of drugs as Cox-2 inhibitors.

2. This action seeks, *inter alia*, emergency notice to all class members to assure notification to individuals taking Vioxx and Celebrex of important research recently presented to the Food & Drug Administration ("FDA") that patients taking Vioxx and Celebrex have a higher risk of heart attacks than patients taking other pain reliever medication to treat their osteoarthritis. Both of these drugs, belong to a class of drugs now as Cox-2 inhibitors.

3. Merck and Pharmacia have consistently marketed Vioxx and Celebrex as highly effective, pain relief drugs for patients suffering from osteoarthritis as compared with more traditional less costly drugs used to treat osteoarthritis. As demonstrated by Merck's own research, users of Vioxx were four times as likely to suffer heart attacks as compared to other less expensive medications, or combinations thereof. Under the circumstances, Vioxx and Celebrex should no longer be used as a primary drug in the treatment of osteoarthritis. Nonetheless, Merck and Pharmacia have taken no affirmative steps to communicate this critical information to class members.

4. Plaintiff seeks emergency notice to class members and revised patient warnings, in the form of additional medical labeling which is presently being considered by the FDA, so that class members will be apprised of these findings. Notice to patients, as opposed to physicians, is required in order to ensure that persons taking the drug will receive this critical information.

5. Absent emergency notice and revised patient warnings, hundreds or thousands of individuals may unwittingly continue osteoarthritis treatment with Vioxx and Celebrex based on the erroneous assumption that

Vioxx and Celebrex are safer and more effective treatments than other traditional and less costly drugs. Upon receiving the notice, class member will likely go off Vioxx and Celebrex treatment for osteoarthritis, or at the very least use a combination of drugs to treat osteoarthritis, which would have superior results. Class members should be afforded the opportunity to make this informed choice.

6. Plaintiff [illegible] refund of all amounts paid for the purchase of Vioxx and Celebrex, as well as all other ascertainable economic losses suffered, including medical expenses as a result of consulting with physicians regarding this information, and all such other relief as he and the Class are otherwise entitled to, including reasonable attorneys' and expert fees.

PARTIES

7. Plaintiff Mary Lombardozzi is a resident of, and citizen of, the State of New York. At all times relevant herein, plaintiff ingested Vioxx which was prescribed to him for osteoarthritis and was unaware of the serious shortcomings of the drug set forth herein.

8. Plaintiff Dominick Lettieri is a resident of, and citizen of, the State of New York. At all times relevant herein, plaintiff ingested Vioxx which was prescribed to him for osteoarthritis and was unaware of the serious shortcomings of the drug set forth herein.

9. Defendant Merck has its principal place of business at New York, New York and is incorporated in the State of New Jersey. At all times relevant hereto, Merck was engaged in the business of manufacturing the pharmaceutical Vioxx. Merck does substantial business in the State of New York and in this federal district, and

at all times relevant herein, it developed, manufactured and sold interstate commerce and in the State of New York the Vioxx.

10. Defendant Pharmacia has its principal place of business in the State of New Jersey. At all times relevant hereto, Pharmacia was engaged in the business of manufacturing the pharmaceutical Celebrex. Pharmacia does substantial business in the State of New York and in the federal district, and at all times relevant herein, its subsidiary, G.D. Searle developed, manufactured and co-marketed Celebrex with Pfizer in interstate commerce and in the State of New York.

11. Defendant Pfizer has its principal place of business at New York, New York and is incorporated in the State of Delaware. At all times relevant hereto, Pfizer was engaged in the business of co-marketing with Pharmacia's subsidiary, G.D. Searle the pharmaceutical Celebrex. Pfizer does substantial business in the State of New York and in this federal district, and at all times relevant herein, sold in interstate commerce and in the State of New York the aforementioned drug.

JURISDICTION

12. Plaintiff alleges an amount in controversy in excess of $75,000 exclusive of interest and Court costs, as to himself and each member of the proposed Class.

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) because the amount controversy exceeds $75,000, as to the plaintiff and every member of proposed Class, because the individual plaintiffs damage claims exceed said amount and because of the Class has an undivided interest in obtaining injunctive/equitable relief, including emergency notice,

revised drug warnings and medical monitoring, that exceeds $75,000 in value.

14. There is complete diversity of citizenship between plaintiff and defendant.

FACTUAL ALLEGATIONS

15. At all times relevant, defendants, itself, or by use of others, did manufacture, create, design, test, label, package, distribute, supply, market, sell, advertise, and otherwise distribute, in interstate commerce, the products Vioxx and Celebrex.

16. Vioxx and Celebrex are Cox-2 inhibitor which reportedly reduces pain and inflammation, while also significantly reducing incidents of stomach ulcers commonly associated with pain relievers like aspirin and ibuprofen. Osteoarthritis is treated for the purposes of reducing inflammation, selling, stiffness and joint pain.

17. There are over 1 million users of Vioxx and Celebrex nationwide and annual sales of Vioxx and Celebrex worldwide provide defendants Merck, Pharmacia and Pfizer with a combined $4 billion in sales in 2000.

18. Merck, Pharmacia and Pfizer have consistently marketed Vioxx and Celebrex as a highly effective, osteoarthritis drug as compared with more traditional and less costly drugs used to treat osteoarthritis.

CLASS ACTION ALLEGATIONS

19. Plaintiff brings this action as a class action for equitable, injunctive and declaratory relief as well as

monetary relief pursuant to Federal Rules of Civil Procedure Rule 23 on behalf of a class consisting of all persons in the United States, including their successors in interest, who have ingested Vioxx and Celebrex for osteoarthritis at all times relevant herein (the "Class").

20. Plaintiff is a member of the Class he seeks to represent. The members of the Class, thousands of individuals, are so numerous that joinder is impracticable and would involve thousands of litigants.

21. There are questions of law and fact common to the Class including, but not limited to:

(a) Whether Vioxx and Celebrex are hazardously less effective in reducing inflammation, swelling, stiffness and joint pain as compared with the more traditional and less costly non-prescription medication such as aspirin and ibuprofen used to treat osteoarthritis;

(b) Whether defendants have failed to adequately warn of the hazardous shortcomings of Vioxx and Celebrex in reducing inflammation, swelling, stiffness and joint pain, as compared to other forms of osteoarthritis treatments;

(c) Whether emergency notice and revised patient warnings should be disseminated to class members;

(d) Whether defendants negligently designed, manufactured, warned of and/or marketed Vioxx and Celebrex;

(e) Whether defendants conducted, either directly or indirectly, appropriate pre- and post-release testing of Vioxx and Celebrex; and

(f) Whether users of Vioxx and Celebrex are entitled to monetary relief.

22. The claims of the named plaintiff are typical of the claims of the Class in that the named plaintiff and the members of the Class used Vioxx and Celebrex for the treatment of osteoarthritis.

23. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class and common issues predominate. Plaintiff has retained counsel competent and experienced in complex class actions.

24. Notices can be provided to class members by a combination of published notice, Internet notice and first-class mail using techniques and forms of notice similar to those customarily used in drug-related product liability, personal injury and other consumer class actions.

25. Plaintiff seeks, *inter alia* injunctive relief in the form of emergency notice and revised drug warnings to more adequately advise Vioxx and Celebrex users of the drugs' performance in relation to the other available treatment for osteoarthritis and a Court-order and supervised medical monitoring program funded by defendants.

26. Class certification is appropriate because defendants have acted, or refused to act, on grounds generally applicable to the Class, making appropriate preliminary and final injunctive and declaratory relief consisting of emergency notice, revised patient warnings and medical monitoring with respect to plaintiff and the class members. In addition, the prosecution of separate actions by or against individual member of the Class would create a risk of incompatible standards of conduct

for defendants and inconsistent or varying adjudications for all parties. A class action is also superior to other available methods for the fair and efficient adjudication of this action.

FIRST CLAIM FOR RELIEF
STRICT PRODUCT LIABILITY
(FAILURE TO WARN)

27. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

28. Defendants are the manufacturers and/or suppliers of Vioxx and Celebrex.

29. Vioxx and Celebrex manufactured and/or supplied by defendants, was and is unaccompanied by adequate warnings regarding the higher risk of heart attacks for patients ingesting these drugs than those patients taking more traditional non-prescription pain relief medication.

30. Defendants failed to perform adequate testing prior to its introduction in that adequate testing would have shown that patients taking Vioxx and Celebrex had an increased risk of heart attacks than those patients taking more traditional non-prescription pain relief medication.

31. Vioxx and Celebrex manufactured and/or supplied by defendants was defective due to inadequate post-marketing warnings or instructions because, after the manufacturers knew or should have known that Vioxx and Celebrex posed a greater risk to patients taking these drugs than those patients taking more traditional non-prescription pain relief medications.

32. As the producing cause and legal result of the defective or hazardous condition of Vioxx and Celebrex as manufactured and/or supplied by defendants, and as a direct and legal result thereof, plaintiff and other class members require reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses and required updated warnings and emergency notice. Absent such equitable relief, plaintiff and other members of the Class will suffer irreparable injury for which there is no adequate remedy at law.

SECOND CLAIM FOR RELIEF
STRICT PRODUCT LIABILITY

33. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

34. Defendants are the manufacturers and/or suppliers of Vioxx and Celebrex.

35. The Vioxx and Celebrex manufactured and/or supplied by defendants was defective or hazardous in design or formulation in that, when it left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

36. Alternatively, the Vioxx and Celebrex manufactured and/or supplied by defendants was defective or hazardous in design or formulation, in that, when it left the hands of the manufacturers and/or suppliers, it was unreasonably dangerous, more dangerous than an ordinary consumer would expect and more dangerous than other forms of osteoarthritis pain relief treatments.

37. The Vioxx and Celebrex manufactured and/or supplied by defendants was defective or hazardous due to inadequate warning or instruction because the manufacturers knew or should have known that those products posed a great risk to patients taking then those patients taking more traditional non-prescription pain relief medications.

38. As the producing cause and legal result of the defective or hazardous condition of Vioxx and Celebrex as manufactured and/or supplied by defendants, and as a direct and legal result thereof, plaintiff and other Class members require reasonable and necessary health care, attention and services and did incur medical, health, incidental and related expenses and require updated warnings and emergency notice. Absent such equitable relief, plaintiff and members of the Class will suffer irreparable injury for which there is no adequate remedy at law.

THIRD CLAIM FOR RELIEF
NEGLIGENCE

39. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

40. Defendants have a duty to exercise reasonable care in the manufacture, sale and/or distribution of Vioxx and Celebrex into the stream of commerce, including a duty to assure that the products work effectively for their intended use which reasonably and foreseeable included reduction of inflammation, swelling, stiffness and joint pain without increasing the likelihood of heart attack by patients ingesting these products.

41. Defendants have failed to exercise reasonable care in the manufacture, sale, testing, equality assurance, quality control and/or distribution of Vioxx and Celebrex into interstate commerce in that defendants have known or should have known that Vioxx and Celebrex posed a great risk to patients taking them than those patients taking more traditional non-prescription pain relief medications.

42. Defendants were negligent in the design, manufacture, testing, advertising, warning, marketing and sale of Vioxx and Celebrex in that it:

(a) Failed to use reasonable care in designing and manufacturing Vioxx and Celebrex so as to avoid the aforementioned risk to individuals when Vioxx and Celebrex was being used for pain management associated with osteoarthritis.

(b) Failed to accompany its product with proper warnings regarding all possible adverse effects associated with the use of Vioxx and Celebrex.

(c) Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the effective of Vioxx and Celebrex.

(d) Failed to provide adequate training to medical care providers for appropriate use of Vioxx and Celebrx;

(e) Failed to warn plaintiff and other members of the Class, prior to actively encouraging the sale of Vioxx and Celebrex, either directly or indirectly, orally or in writing that Vioxx and Celebrex poised a significant risk of heart

attack over and above traditional non-prescription pain relief medication.

(f) Was otherwise careless or negligent.

43. Despite the fact that defendants knew or should have known that Vioxx and Celebrex and posed a significant risk to patients taking these drugs than those patients taking more traditional non-prescripton pain relief medication, defendants have continued to market Vioxx and Celebrex to consumers, including plaintiff, when there were safer, more effective and less expensive methods of pain relief from osteoarthritis.

44. Defendants have known or should have known that consumers such as plaintiff would suffer foreseeable injury as a result of defendants' failure to exercise ordinary care, including irreparable injury absent equitable relief, as described above.

45. Defendants' negligence was a proximate cause of plaintiff's and class members' economic loss which they have suffered and continue to suffer.

FOURTH CLAIM FOR RELIEF
BREACH OF EXPRESS WARRANTY

46. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

47. Defendants have expressly warranted that Vioxx and Celebrex are safe and effective for the treatment of osteoarthritis.

48. Vioxx and Celebrex does not conform to this express representation in that they fails to advise users of the increased risk of heart attack, while other less

expensive non-prescription treatments do not present this risk.

49. As direct and proximate result of the breach of said warranties, plaintiff and class members suffered economic loss in amounts to be proven at trial.

FIFTH CLAIM FOR RELIEF
BREACH OF IMPLIED WARRANTY

50. Plaintiff incorporates by reference all other paragraphs of this complaint as iffully set forth herein and further alleges as follows:

51. At the time defendants marketed, sold, and distributed Vioxx and Celebrex, defendants knew that the use for which Vioxx and Celebrex were intended and impliedly warranted the product to be of merchantable quality and fit for such use.

52. Plaintiff and other class members and their physicians reasonably relied upon the skill and judgment of defendants as to whether Vioxx and Celebrex was of merchantable quality and fit for its intended use.

53. Contrary to such implied warranty, Vioxx and Celebrex were not of merchantable quality or fit for its intended use, because the product was and is unfit for the ordinary purposes of which it was used as described above.

54. As a direct and proximate result of the breach of implied warranty, plaintiff and other members of the Class suffered economic loss as alleged herein.

CLASS ACTION INJUNCTIVE, EQUITABLE AND MONETARY RELIEF

55. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

56. Defendants have a continuing duty to warn plaintiff, the Class and the public of all potential risks and dangers of which it becomes or should become aware of. There have been studies underway regarding these risks and dangers. As a proximate result of defendants' conduct as described herein, plaintiff, on behalf of himself and all other similarly situated, is entitled to damages and/or equitable relief in the form of emergency notice, revised drug warnings and/or equivalent remedial and corrective action, to accurately reflect and publicize the known effects of Vioxx and Celebrex, at defendants' expense.

57. Defendants should be required to provide information, including appropriate and updated product warnings to individuals who use and/or have previously use Vioxx and Celebrex for osteoarthritis to apprise them of timely information concerning the drug and the relative riskiness of its use.

58. Plaintiff's and class members' increased risk of heart attack and certain other serious cardiac events as a result of their use of Vioxx and Celebrex makes periodic diagnostic and medical examinations necessary and reasonable. Easily administered, cost-effective medical monitoring procedures exist which may be applied to plaintiff and members of the Class.

59. Plaintiff and other members of the Class are also entitled to damages, as well as their estates or heirs, for wrongful death, pain, suffering and lost earnings.

WHEREFORE, PLAINTIFF PRAYS FOR RELIEF AS FOLLOWS

60. Wherefore, Plaintiff prays for relief as follows:

(a) That this action be certified as a class action on behalf of the proposed class of individuals who have ingested Vioxx and/or Celebrex for osteoarthritis, that the named plaintiffs be designated as representative of the Class and that named counsel be designated Class counsel;

(b) Creation of a comprehensive, court-supervised program which will:

(1) Locate and notify Vioxx and Celebrex users that users of Vioxx and Celebrex are more likely to suffer a heart attack as compared with patients taking the more traditional and less costly non-prescription medications or combinations thereof;

(2) Create a court-supervised trust fund, paid for by defendants, to finance a medical monitoring program to deliver services, including but not limited to testing, preventive screening and surveillance for conditions resulting

from, or potentially resulting from consumption of Vioxx and Celebrex.

(3) Provide class members with revised warnings on drug labels and packages; and

(4) Include new warnings on Merck and Pharmacia's Internet websites and in Vioxx and Celebrex's U.S. Product Prescribing Information, which appears in the Physicians' Desk Reference;

(c) Award plaintiff and the Class damages incidental to their procurement and ingestion of Vioxx and Celebrex.

(d) Order defendants to refund and make restitution of all monies acquired from the sale of Vioxx and Celebrex to plaintiff and the Class;

(e) Attorneys' fees, expenses, and costs of this action; and

(f) Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial in this action.

Dated: May 23, 2001 /s/ Nicholas A. Gravante, Jr.

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SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: HUNTERDON COUNTY

Case No. HNT L530-01

JOHN ASTIN, INDIVIDUALLY AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, PLAINTIFF
v.
MERCK & CO., INC. DEFENDANT

CLASS ACTION COMPLAINT

Plaintiff, by his attorneys, alleges as follows upon information and belief pursuant to the investigation of his counsel, except as to the allegations that pertain to Plaintiff which are based upon Plaintiff's personal knowledge:

1. This is an action for economic damages only relating to defendant's sale, marketing, advertising, promotion and/or distribution of the blockbuster arthritis drug Vioxx. Plaintiff brings the action on behalf of himself and all other New Jersey consumers of Vioxx who have been deceived and injured by Defendant's improper acts and practices as set forth in this Complaint.

The Parties

2. Plaintiff John Astin is a resident of New Jersey who has purchased Vioxx and has been damaged as a result of the acts alleged in this Complaint.

3. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation that has its principal place of business at One Merck Drive, Whitehouse Station, New Jersey. At all relevant times, Defendant Merck manufactured, sold, marketed, advertised, promoted and/or distributed Vioxx globally, including in New Jersey. At all relevant times Merck was authorized to conduct business and did substantial business in the State of New Jersey, including the marketing and sale of Vioxx in New Jersey.

4. At all relevant times, Defendant acted by and through its agents and/or employees who were acting within the course, scope and authority, apparent or actual, of such agency and/or employment. Where it is alleged in this Complaint that Defendant committed any act and/or omission or engaged in any conduct, it is meant that the Defendant committed that act and/or omission or engaged in that conduct by and through its agents and/or employees, and that the act, omission or conduct, occurred with the full authorization or ratification of each Defendant and/or occurred in the normal and routine course and scope of the agency or employment of Defendant's agent or employee.

Jurisdiction and Venue

5. This case is filed pursuant to R. 4:3-2(A), with jurisdiction in Hunterdon County, where Defendant Merck has its headquarters and where the causes of actions arose that are set forth in this Complaint.

6. This suit is brought under the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 ***et seq.*** (hereinafter the "Consumer Fraud Act") and other legal theories to recover damages and other relief, including

the costs of suit as well as reasonable attorney fees and expert fees, for the damages Plaintiff has sustained as a result of Defendant's acts and omissions in violation of the Consumer Fraud Act and other laws.

CLASS ACTION ALLEGATIONS

7. Plaintiff brings this action as a class action for monetary relief on behalf of a class of all persons who were New Jersey residents at the time they purchased Vioxx or who purchased Vioxx in New Jersey (the "Class"). Plaintiff expressly disclaims any intent to seek any recovery for personal injuries suffered or which may be suffered by any Class member.

8. Excluded from the Class are Merck, Merck's officers and directors at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Merck has or had a controlling interest.

9. Plaintiff is a member of the Class that Plaintiff seeks to represent.

10. The Class is so numerous that joinder of all members is impractical. Although Plaintiff does not yet know the exact size of the Class, upon information and belief based on published reports, the Class includes at least thousands of consumers. Accordingly, joinder is impracticable.

11. There are numerous questions of law and fact common to the Class including:

(a) Whether Defendant misrepresented material facts concerning Vioxx to Plaintiff and the Class;

(b) Whether Defendant's misrepresentations and omissions violated the New Jersey Consumer Fraud Act;

(c) Whether Defendant's product labels, marketing and promotional materials and advertisements were misleading and misrepresented the safety and efficiency of Vioxx;

(d) Whether Defendant negligently manufactured, promoted and/or marketed Vioxx; and

(e) Whether Plaintiff and the Class are entitled to monetary relief.

12. Plaintiff's claims are typical of the claims of the Class in that Plaintiff and the members of the Class purchased Vioxx.

13. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class and common issues predominate. Plaintiff has retained counsel competent and experienced in complex class actions.

14. Notice can be provided to Class members by a combination of published notice, Internet notice and/or first-class mail using techniques and forms of notice similar to those customarily used in consumer class actions.

15. Class certification is appropriate because Merck has acted, or refused to act, on grounds generally applicable to the Class. A class action is also superior to other available methods for the fair and efficient adjudication of this action.

Merck Has Repeatedly Misled Consumers, Including Plaintiff and the Class, About Vioxx

16. At all relevant times Merck has engaged in a concerted fraudulent and deceptive effort to obtain Food and Drug Administration ("FDA") approval for Vioxx and to reap the benefits of Vioxx's commercial success by misleading the public about Vioxx through misrepresentations and omissions and other deceptive practices made to health care providers and through other advertising.

17. On May 5, 1999 the United States Food and Drug Administration (the "FDA") approved Vioxx as a new arthritis drug. Following the FDA's approval of Vioxx, Merck manufactured and marketed Vioxx.

18. Since it received FDA approval, Vioxx has generated billions of dollars in annual sales for Merck mostly as a result of aggressive marketing campaigns in which Merck has repeatedly misrepresented Vioxx as safe an effective. In particular, Merck has repeatedly touted Vioxx's benefits over much cheaper pills and over its main competitor Celebrex, and has portrayed Vioxx as causing fewer side effects, such as gastrointestinal and cardiovascular problems, than other drugs, including aspirin and Celebrex.

19. Merck also promoted Vioxx by emphasizing small differences in the risks and benefits involved in its use as compared to its main competitor, Celebrex. As Forbes.com recently noted, "small advantages and tiny flaws start to look gigantic to the companies."

20. On December 16, 1999, the FDA wrote to Merck and gave it "written notification" that its promotional activities for Vioxx were false and

misleading and "misrepresented Vioxx's safety profile." Merck, however, continued its misrepresentations and continued to generate tremendous sales of its lucrative drug Vioxx.

21. On September 17, 2001, in yet another attempt to stop Merck from misleading consumers, the Director of the FDA's Division of Drug Marketing faxed a letter directly to Raymond Gilmartin, the President and CEO of defendant Merck. At the top of the letter, in bold types and all capital letters the FDA wrote "**WARNING LETTER**". That Warning Letter informed Merck that the FDA had reviewed Defendant's "promotional activities and materials for the marketing of Vioxx " and "has concluded that they are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug and Cosmetic Act and applicable regulations." (emphasis supplied). The FDA also criticized Merck because of the "seriousness of these violations and the fact that [Merck's] violative promotion of Vioxx has continued despite [the FDA's] prior written notification regarding similar violations." (emphasis supplied).

22. In the Warning Letter, the FDA explained that Merck's promotional activities repeatedly:

(a) "minimize[d] the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study";

(b) "misrepresent[ed] the safety profile for Vioxx";

(c) "discount[ed] the fact that in the VIGOR study, patients on Vioxx were observed to have a four or five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steriodal

anti-inflammatory drug (NSAID), Naprosyn (Naproxien).";

(d) "omit[ted] important risk information";

(e) "ma[d]e unsubstantiated superiority claims against other NSAIDs, and promote[d] Vioxx for unapproved uses and an unapproved dosing regimen";

(f) "misrepresent[ed] Vioxx's safety profile by minimizing the potentially serious risk of significant bleeding that can result from using Vioxx and warfarin concomitantly.";

(g) "fail[ed] to present serious and significant risks associated with Vioxx therapy" such as Vioxx's contraindications and warnings about "the possibility of serious GI toxicity such as bleeding, ulceration, or perforation in patients taking Vioxx";

(h) misled the public about the competing drug Celebrex;

(i) made the misleading suggestion that "Vioxx is effective for the treatment of rheumatoid arthritis when this has not been demonstrated";

(j) misled the public by suggesting that "Vioxx is safe and effective for other unapproved uses such as the prevention of cancer and invasive cancer, and for the treatment of Alzheimer's disease and gout".

23. The FDA also criticized Merck for making the "simply incomprehensible" claim that Vioxx has a "favorable cardiovascular safety profile" when in fact "serious cardiovascular events were twice as frequent in the Vioxx treatment group (101 events, 2.5%) as in the Naproxen treatment group (46 events, 1.1%) in the VIGOR study."

24. On August 22, 2001, an article in The Wall Street Journal revealed to the consumer public for the first time that questions existed about the safety and efficacy of Vioxx. That article reported that a study published in the Journal of the American Medical Association concluded that "patients taking Vioxx had more than twice as many heart attacks, strokes and other cardiovascular events as patients getting an older, generic arthritis drug, Naproxen.".

25. This was particularly striking because, as The Wall Street Journal reported, the "purported side-effect advantages were what fueled the growth of [Vioxx] in the first place" and Vioxx "caught on because doctors and patients believed [Vioxx] less likely to cause gastrointestinal problems."

26. One doctor who was quoted in The Wall Street Journal article, Dr. Sharon Levine at Permanente Medical Group at Kaiser Permanente, aptly noted that because of Merck's misrepresentations and deceptive practices "consumers are paying millions and millions for drugs that, for most of them, appear to have no clinical benefit" over much cheaper pills.

27. As a result of Merck's misleading marketing and promotional practices in connection with selling Vioxx, Plaintiff and the other Class members who purchased Vioxx based upon Defendant's improper practices have suffered millions of dollars of economic damages and other injury.

COUNT I

New Jersey Consumer Fraud Act

28. Plaintiff realleges and incorporates by reference the allegations set forth above.

29. Merck, in its capacity as the manufacturer, distributor, marketer and seller of Vioxx is a "person" for the purposes of the Consumer Fraud Act, as codified in N.J.S.A. 56:8-1, ***et seq***.

30. Plaintiff and the other members of the Class purchased and used Vioxx for personal use and suffered ascertainable loss as a result of Defendant's actions in violation of the Consumer Fraud Act.

31. Prescription drugs are "merchandise" as defined in N.J.S.A. 56:8-1(c).

32. Merck violated the Consumer Fraud Act, N.J.S.A. 56:8-1, ***et seq***., by engaging in unconscionable commercial practices, through deception, fraud, and making false promises and misrepresentations, including, but not limited to, the following:

(1) Merck omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Vioxx, including, but not limited to, the risks of serious damage from cardiovascular problems. Furthermore, Merck has purposefully downplayed and/or understated the serious nature of the risks associated with Vioxx;

(2) Merck falsely and deceptively misrepresented or knowingly omitted, suppressed, or concealed material facts regarding the safety and efficacy of Vioxx;

(3) Merck knew or should have known, and would have known, had appropriate testing been done, that the use of Vioxx caused serious side effects including cardiovascular problems;

(4) Merck engaged in calculated silence despite its knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of Vioxx, and did so because the prospect of huge future profits outweighed health and safety issues, all to the detriment of Plaintiff and the other members of the Class;

(5) Merck purposefully downplayed the side effects or provided misinformation about adverse reactions and potential harms from Vioxx, and succeeded in persuading large segments of the medical community to prescribe Vioxx despite both a lack of efficacy and the significant dangers as set forth herein;

(6) Merck had a clear post-manufacture duty to warn which arose when it knew, or with reasonable care should have known, that Vioxx was injurious.

33. Merck breached its duty of care, constituting negligence, as follows:

(a) Merck failed to conduct adequate testing of the drug;

(b) Merck failed to properly monitor and evaluate the drug's effect;

(c) Merck concealed the clinical experience of the drug from the medical community, which included the medical personnel treating Plaintiff and the other members of the Class;

(d) Merck failed to fulfill the standard of care required of a reasonable, prudent pharmaceutical company engaged in the manufacture, distribution, promotion and sale of a drug intended specifically for use by individuals suffering from arthritis and other ailments;

(e) Merck failed to adequately warn of the dangers which it knew or should have known that the drug posed;

(f) Merck placed the drug in commerce for sale and recommended its use without adequately warning users of risks associated with the use of the drug;

(g) Merck failed to properly market, advertise or distribute the drug, an inherently dangerous product, when it knew or should have known that there existed

danger to users of Vioxx arising from the foreseeable and recommended use of the product;

(h) Merck failed to disclose to the public, to the Class and to the Plaintiff, facts relative to the drug being unsafe and a cause of dangerous side effects or complications;

(i) Merck failed to heed or further investigate adverse reaction reports submitted by the medical community in order to determine whether the drug should be withdrawn from the market.

34. Merck's actions as set forth herein constitute knowing omission, suppression, or concealment of material facts, made with the intent that others will rely upon such concealment, suppression or omission, in connection with the marketing of Vioxx in violation of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-2, ***et seq***.

35. Such unconscionable commercial practices make Merck liable to Plaintiff and the Class under N.J.S.A. 56:8-2, which provides that "[a]ny person violating the provisions of the act shall be liable for a refund of all moneys acquired by means of any practice declared to be unlawful."

36. As a proximate result of these violations of the Consumer Fraud Act, Plaintiff and the Class suffered ascertainable economic loss, including the purchase price of the drugs, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs.

37. As a direct and proximate result of using Vioxx, Plaintiff and the other members of the Class

suffered economic loss in an amount to be established at trial.

38. Merck is further liable to Plaintiff and the Class for treble damages under N.J.S.A. 56:8-13, 19.

39. Plaintiff and the Class are also entitled to recover attorney's fees and costs, as well as treble damages, from Merck under N.J.S.A. 56:8-19.

WHEREFORE, Plaintiff and the Class respectfully request that they be granted relief against Merck as contained in the Prayer For Relief.

COUNT II

Fraud and Misrepresentation

40. Plaintiff repeats and realleges the allegations set forth above.

41. Merck failed to publish adequate precautionary statements warning consumers as more information above adverse reactions became available. Merck continued to design, manufacture and market the product and fervently promote the beneficial and safe use of the drug.

42. The product warnings in effect were inadequate to alert consumers to actual risks associated with this drug that were then known to Merck.

43. Plaintiff and the Class purchased and used Vioxx in reliance upon the express and implied representations of material facts made by Merck and its agents directly and indirectly through uniform advertisements, sales literature and other forms of marketing.

44. Plaintiff and the Class decided to use Vioxx reasonably relying on Merck and its agents to disclose known defects and side effects of the drug. Merck's misrepresentations, omissions and concealment of material facts were made to induce Class members to rely upon them and purchase and use Vioxx.

45. Merck knew or recklessly disregarded the fact that its statements regarding Vioxx were false, misleading, incomplete, and/or untrue when made.

46. The uniform misrepresentations, misleading statements, material omissions, and the fraudulent concealment of material facts by Merck or its agents were made with the intention to deceive and defraud or to conceal the truth about the safety and efficacy of Vioxx.

47. Merck's uniform misrepresentations, misleading statements, material omissions, and fraudulent concealment of material facts concerning Vioxx were made to induce the purchase and use of Vioxx by Plaintiff and the Class in order to increase sales and profits.

48. Plaintiff and the Class had no knowledge of the falsity or incompleteness of Merck's statements and representations when they purchased the Vioxx that was manufactured, marketed, distributed, and sold by Merck or their agents.

49. Plaintiff and the Class had a right to and did rely on Merck's uniform statements and representations. Merck's uniform statements and representations, express or implied, concerning the safety and effectiveness of Vioxx were material to the decision to purchase and use that drug, in that Class members would not have purchased and used the drug if they had

known that such statements and representations of Merck were false, misleading, incomplete, and untrue.

50. At all times, Merck failed to disclose adequately material adverse information regarding the dangerous side effects of Vioxx, as alleged above.

51. Merck was under a duty to disclose the defective and unsafe nature of Vioxx to consumers such as Plaintiff and the Class. Merck had sole access to material facts concerning the defective nature of Vioxx and Merck knew that consumers could not have reasonably discovered the defects or Merck's misrepresentations or omissions.

52. Merck's omissions were made deliberately, willfully and maliciously to mislead consumers into purchasing and using Vioxx and believing that the drug was safe and not defective.

53. Class members had no way to determine that Merck was making these material misrepresentations or fraudulently concealing material facts. Had Merck disclosed the material information regarding the unsafe and defective nature of Vioxx, Plaintiff and Class members would have been aware of the defect and would not have purchased and used the drug or continued to believe that the drug was fit for its intended purpose.

54. By reason of Merck's fraudulent concealment, material misrepresentations, misleading statements, and/or material omissions, Plaintiff and the other Class members have been damaged in an amount to be established at trial.

55. Because Merck's conduct in perpetrating the fraud described above was malicious, willful, wanton, and oppressive, or in reckless disregard of the rights of the

Class, the imposition of punitive damages against Merck is warranted.

WHEREFORE, Plaintiff and the Class respectfully request that they be granted relief against Merck jointly and severally, as contained in the Prayer For Relief.

COUNT III

Breach of Warranty

56. Plaintiff repeats and realleges each allegation above.

57. Through its public statements about Vioxx, its descriptions of Vioxx and its promises relating to Vioxx, Merck expressly and impliedly warranted that Vioxx was both efficacious and safe for its intended use.

58. These warranties came in the form of (i) publicly made written and verbal assurances of safety and efficacy by Merck pursuant to and following FDA approval, including but not limited to statements of clinical data that purported to report the safety and efficacy of Vioxx; (ii) press releases, interviews, and dissemination via the media of uniform promotional information that was intended to create demand for Vioxx, but which contained material misrepresentations and utterly failed to warn of the risks of Vioxx; (iii) verbal assurances made by defendant's sales force to prescribing physicians and the public about the safety and efficacy of Vioxx and the downplaying of the risks associated with Vioxx; (iv) false and misleading written information supplied by Defendant.

59. Plaintiff further alleges that all of the aforementioned written materials are known to Merck

and in its possession, and it is Plaintiff's reasonable belief that these materials shall be produced by Merck and be made of record once Plaintiff has the opportunity to conduct discovery.

60. When Merck made these express and implied warranties, Merck knew the purpose for which Vioxx was to be used and warranted it to be in all respects safe, effective and proper for such purpose.

61. Merck itself drafted the documents and/or made the statements upon which these warranty claims are based, and in so doing, defined the terms of those warranties.

62. Vioxx does not conform to Defendant's representations in that Vioxx is not safe and produces serious side effects.

63. As such, Vioxx did not conform to Defendant's promises, descriptions or affirmations of fact and was not adequately packaged, labeled, promoted or fit for the ordinary purposes for which such drugs are used.

64. Defendant therefore breached its warranties to Plaintiff in violation of N.J.S.A. 12A:2-313, codifying the Uniform Commercial Code: (i) by manufacturing, marketing, packaging, labeling, and selling Vioxx to consumers, such as Plaintiff and the Class, in a way that misstated the risk of injury, without warning of or disclosing that risk and/or without modifying or excluding the applicable warranties; (ii) by manufacturing, marketing, packaging, labeling, and selling Vioxx to Plaintiff and the Class and causing damages as well be established at trial.

WHEREFORE, Plaintiff and the Class respectfully request that they be granted relief against Defendant contained in the Prayer For Relief.

COUNT IV

Negligence and Negligent Misrepresentation

65. Plaintiff repeats and realleges each and every allegation above.

66. Defendant owed a duty to consumers of Vioxx to use reasonable care in designing, manufacturing, promoting, supplying, and selling Vioxx and to disseminate truthful information about Vioxx.

67. Defendant breached its duty of care, constituting negligence, as follows:

(a) Omitting and misrepresenting material facts about the safety and efficacy of Vioxx and, as a result, artificially inflating the price that Plaintiff and the Class paid for Vioxx;

(b) Defendant failed to properly monitor and evaluate the drug's safety and efficacy;

(c) Defendant concealed the clinical experience of the drug;

(d) Defendant failed to fulfill the standard of care required of a reasonable, prudent pharmaceutical company engaged in the manufacture of a drug intended specifically for use by individuals suffering from arthritis;

(e) Defendant failed to adequately warn of the dangers which it knew or should have known that the drug posed;

(f) Defendant failed to report adverse results of tests to the FDA, as required by law;

(g) Defendant placed the drug in commerce for sale and recommended its use without adequately warning of risks associated with the use of the drug;

(h) Defendant failed to properly market, advertise or distribute the drug, an inherently dangerous product, when it knew or should have known, that there existed dangers to users of Vioxx arising from the foreseeable and recommended use of the product;

(i) Defendant failed to disclose to consumers facts relative to the drug being unsafe and a cause of dangerous side effects or complications;

(j) Defendant failed to heed or further investigate adverse reaction reports submitted by the medical community in order to determine whether the drug should be withdrawn from the market.

68. As a direct and proximate result of Defendant's actions, Plaintiff and the Class have been damaged in an amount to be established at trial.

69. Defendant has, at all times material hereto, manufactured, promoted, sold, and distributed the drug in a manner which constituted gross, willful, malicious, reckless, and outrageous disregard for the consequences of their actions and omissions, including the criminal and culpable disregard for the consequences of its actions and omissions on consumers such as Plaintiff and the Class.

70. Defendant had a duty to exercise reasonable care in the manufacture, sale, promotion, and/or distribution of Vioxx including a duty to:

(a) make truthful statements about Vioxx and its safety and efficacy;

(b) correct omissions and misrepresentations of material fact concerning Vioxx and its safety and efficacy;

(c) warn consumers of dangerous side effects; and

(d) disclose adverse material facts when making representations of facts.

71. Defendant failed to exercise reasonable care in the manufacture, sale, promotion and/or distribution of Vioxx into the stream of commerce because defendant knew or should have known that it had omitted and misrepresented material facts concerning the drug and knew or should have known that the use of Vioxx created a high risk of unreasonable, dangerous side effects, including side effects such as cardiovascular problems.

72. Defendant breached its duty of reasonable care and its duty to disclose material adverse facts to Plaintiff by failing to use reasonable care in the design, manufacture, promotion and sale of Vioxx; failing to provide sufficient accompanying warnings and/or indications concerning Vioxx and its health effects; failing to conduct adequate testing; and failing to ensure that Vioxx was used only in a manner for which it had been approved and which was safe.

73. Although Defendant knew or should have known that Vioxx caused unreasonable, dangerous side effects, defendant continued to market and promote Vioxx unlawfully.

74. Defendant knew or should have known that Plaintiff and the Class would foreseeably suffer injury as a result of Defendant's failure to exercise reasonable care as described above.

75. Defendant intended that Plaintiff and the Class would rely upon its representations and statements and would rely on Defendant and its agents to inform them truthfully, accurately and fully about Vioxx.

76. At the time of defendant's misrepresentations, misleading statements and/or omissions about Vioxx, Plaintiff and the Class were ignorant of their falsity. Plaintiff and the Class relied upon Defendant's superior knowledge and expertise and, justifiably, relied, to their detriment, on Defendant's representations and statements. Had Plaintiff and the Class been aware of the true facts, they would not have purchased or used Vioxx.

77. By virtue of Defendant's negligence and negligent misrepresentations, Defendant has directly, foreseeably and proximately damaged Plaintiff and the Class in an amount to be established at trial.

78. Defendant's actions as described above constitute knowing omission, suppression or concealment of material facts made with the intent that others would rely upon that concealment, suppression or omission.

79. As a result, the imposition of punitive damages against Defendant is warranted.

COUNT V

Unjust Enrichment And Restitution

80. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein and further alleges as follows:

81. As a result of its improper acts set forth in this Complaint, Defendant has realized billions of dollars in sales of Vioxx to consumers, including Plaintiff and members of the Class.

82. Plaintiff and the other Class members would not have purchased Vioxx had they been adequately informed by Defendant or warned of the potential adverse health risks from Vioxx.

83. If Plaintiff proves the allegations of inadequate and untruthful product safety labeling, Defendant would stand to be unjustly enriched if it were permitted to retain its ill-gotten gains. Therefore, the ill-gotten gains should be refunded to Plaintiff and members of the Class.

84. As a result of Defendant's acts described above, Plaintiff and the other members of the Class have suffered ascertainable loss - economic loss that includes the purchase price of the products- for which Defendant is liable to Plaintiff and the Class, plus attorneys' fees and costs.

WHEREFORE, Plaintiff and the Class respectfully request that they be granted relief against Defendant as contained in the Prayer For Relief herein.

PRAYER FOR RELIEF

1. That this action be certified as a Class action on behalf of the proposed class of New Jersey consumers who have purchased Vioxx, that the named plaintiff be designated as the representative of the Class, and that named counsel be designed as Class counsel;

2. That Plaintiff and the Class have and recover compensatory damages under the New Jersey

Consumer Fraud Act of Defendant and that these damages be trebled, and that Plaintiff and the Class have and recover a reasonable attorney's fee and costs pursuant to the New Jersey Fraud Act under Count I of this Complaint;

4. That Plaintiff and the Class have and recover compensatory and punitive damages resulting from Defendant's fraud and misrepresentation under Count II of this Complaint;

5. That Plaintiff and the Class have and recover compensatory damages resulting from Defendant's breach of warranty under Count III of this Complaint;

6. That Plaintiff and the Class have and recover compensatory and punitive damages resulting from Defendant's negligence and negligent misrepresentation under Count IV of this Complaint;

7. That Plaintiff and the Class have and recover economic damages for unjust enrichment and restitution under Count V of this Complaint;

8. For a jury trial on all issues so triable;

9. That the costs of this action be taxed to defendant;

10. For such other and further relief as to this Court deems just, fair and reasonable.

Dated: September 27, 2001

SQUITIERI & FEARON, LLP

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ATTORNEYS FOR PLAINTIFF AND THE CLASS

CERTIFICATION PURSUANT TO R. 4:5-1

The undersigned hereby certifies the following:

That, to the best of my knowledge and belief, this matter in controversy is not the subject of any other action pending in any court or of a pending arbitration proceeding, nor is there any such proceeding contemplated at this time by the Plaintiff. That, to the best of my knowledge and belief, there are no other parties who must be joined in this action.

Dated: September 27, 2001

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ATTORNEYS FOR PLAINTIFF AND THE CLASS

DEMAND FOR JURY TRIAL

PLEASE TAKE NOTICE that the Plaintiff demands trial by jury as to all issues in the above matter.

Dated: September 27, 2001

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ATTORNEYS FOR PLAINTIFF AND THE CLASS

IN THE THIRD JUDICIAL DISTRICT
COURT OF SALT LAKE COUNTY
STATE OF UTAH

Case No. 010908559

DELLA JO SALT, BETTY HOUSEHOLDER, CHARLES EVANS, DON BERCHTOLD, KENNETH C. WINWARD, LEROY GUNN, MARGARET HELEN GOODELL, RICHARD DAVID BACA, SALLY COLE, JOYCE CRAWFORD SAFFORD, BARBARA DE LUCA, WARD WRIGHT, YVONNE O. JACKSON, GORMAN REAGAN, AND STAN GILES, AS INDIVIDUALS; AND CLEMENT PISCITELLO, ALISON HOLLEY AND MEREDITH SIEPER, AS HEIRS OF AUDREY L. PISCITELLO, PLAINTIFFS

v.

MERCK & COMPANY, INC., A CORPORATION, DEFENDANTS

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

INTRODUCTION

This case involves the drug Vioxx (Rofecoxib) which was manufactured, sold, distributed and promoted by Defendant to capitalize on the need of the public to have a pain reliever, similar to Ibuprofen, without any of the known Ibuprofen side effects. Defendant misrepresented that Vioxx was a safe and effective way to relieve osteoarthritis, management of acute pain in adults, and treatment of menstrual pain, when in fact the drug

causes serious medical problems such as an increased risk of cardiovascular events, including strokes, heart attacks and death.

GENERAL ALLEGATIONS

1. This is an action for personal injuries and/or death brought by Plaintiffs, individually or as heirs of a deceased, who have been prescribed and supplied with, received, and who have taken and ingested and consumed Vioxx as researched, designed, formulated, compounded, tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed or otherwise placed in the stream of interstate commerce by Defendant Merck & Company, Inc. This action seeks among other relief, general and special damages and equitable relief in order to enable the Plaintiffs to treat and monitor the dangerous, severe and life-threatening side effects caused by these drugs, including but not limited to edema, changes in blood pressure, cardiovascular events and death.

2. The injuries of Plaintiffs were caused by the wrongful acts, omissions, and fraudulent misrepresentations of Defendant, Merck & Company, all of which occurred within the State of Utah.

3. At all times mentioned herein, Defendant Merck & Company was and now is a corporation doing business in the State of Utah.

4. At all times mentioned herein, Merck & Company, Inc. engaged in the business research, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting,

packaging, and/or advertising for sale or selling the drug Vioxx.

5. At all times mentioned herein, Merck & Company, Inc. was authorized to do business within the State of Utah and did in fact supply the aforementioned products within the State of Utah.

The Plaintiffs

6. Plaintiffs are either the patients who took Vioxx and suffered an injury therefrom or their heirs or personal representatives if the patients died. The name of the patient, the symptoms they experienced after taking Vioxx and the cause thereof are set forth below:

NAME	SYMPTOMS	CAUSE
A. Della Jo Salt	Heart attack	Took Vioxx and was injured as a result.
B. Betty Householder	Strokes	Took Vioxx and was injured as a result.
C. Charles Evans	Cardiac Arrest	Took Vioxx and was injured as a result.
D. Don Berchtold	Stroke	Took Vioxx and was injured as a result.
E. Kenneth C. Winward	Stroke	Took Vioxx for 1 ½ years and was injured as a result.
F. Leroy Gunn	Stroke	Took Vioxx since the beginning of 2001 and was injured as a result.
G. Margaret Helen Goodell	Stroke	Took Vioxx for 1 ½ years and was injured as a result.

NAME	SYMPTOMS	CAUSE
H. Richard David Baca	Heart attack and stroke	Took Vioxx and was injured as a result.
I. Sally Cole	Symptoms of heart attack and stroke	Took Vioxx and was injured as a result.
J. Joyce Crawford Safford	Minor strokes	Took Vioxx and was injured as a result.
K. Barbara De Luca	TIA/Stroke	Took Vioxx and was injured as a result.
L. Ward Wright.	Stroke	Took Vioxx and was injured as a result.
M. Yvonne O. Jackson	Stroke	Took Vioxx and was injured as a result.
N. Gorman Reagan	Heart Attack	Took Vioxx and was injured as a result..
O. Stan Giles	Aneurism / High Blood Pressure	Took Vioxx and was injured as a result.
P. Audrey L. Piscitello (Represented in this suit by her heirs Clement Piscitello, Alison Holley and Meredith Sieper)	Heart attack and heart problems. Died after heart surgery.	Took Vioxx and was injured and died as a result.

7. Each of the individuals named above suffered damages, as set forth in the prayer of the Complaint, which is incorporated herein by reference, as a proximate result of taking Vioxx without being fully and

fairly informed by Defendant Merck & Company, Inc. as to the increased risk of cardiovascular events, including an increase in blood pressure, strokes, heart attacks and death, and by reason thereof, the individuals were not able to make an informed decision on whether or not they wanted to take Vioxx after weighing the benefits and the risks and Defendant Merck & Company, Inc. is liable to Plaintiffs for the reasons set forth in the Eight Causes of Action, infra, which are incorporated herein by reference.

8. Additionally, Clement Piscitello, Alison Holley and Meredith Sieper are heirs of Audrey L. Piscitello and were each deprived of her support, affection and companionship due to the illness and eventual death suffered by Ms. Piscitello as a direct result of the drug Vioxx and its insufficient warnings. These three Plaintiffs seek damages under UTAH CODE ANN. §§ 78-11-7 and 78-11-12.

The Defendant

9. Defendant Merck & Company, Inc. manufactured, marketed, sold, and distributed Vioxx which was ingested by the Plaintiffs.

10. Defendant Merck & Company, Inc. is in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale Vioxx.

11. Defendant Merck & Company, Inc. was and is an American pharmaceutical company, incorporated under the laws of New Jersey, whose principal place of business is One Merck Drive, P.O. Box 100, Whitehouse

Station, New Jersey which at all times relevant manufactured and marketed, sold and distributed Vioxx.

FACTUAL ALLEGATIONS

12. At all times relevant, Defendant, itself, or by and through the use of others, did manufacture, create, design, test, label, sterilize, distribute, supply, prescribe, market, sell, advertise, warn, and otherwise distribute in interstate commerce and in the State of Utah the pharmaceutical product known as Vioxx.

13. Vioxx is the trade name of the generic drug Rofecoxib. Vioxx was and is utilized, prescribed and sold by physicians for pain management and the relief of pain. Vioxx has been widely advertised and marketed by Defendant as a safe and effective pain relief medication.

14. Vioxx is a cycloosygenses-2-specific inhibitor. Vioxx is a non-steriodal anti-inflammatory drug that exhibits anti-inflammatory, analgesic and antipyretic activities in animal models. The mechanism of action of Vioxx is believed to be due to inhibitors of prostaglandin syntheses, via inhibition of cyclooxygenase-2 (Cox-2).

15. Vioxx has been widely advertised by the Defendants as an effective pain reliever.

16. Ibuprofen is a widely used drug used to reduce pain and inflammation. It is estimated that Ibuprofen sales exceed $10 billion per year. Major side effects of Ibuprofen include gastrointestinal problems. Merck & Company, Inc. endeavored to develop a drug with pain relieving and anti-inflammatory qualities that would not harm the user's stomach. Merck & Company, Inc. developed, tested, and obtained FDA approval for Vioxx, a Cox-2 inhibitor designed to replace Ibuprofen.

17. Defendant Merck & Company, Inc. made filing(s) with the United States Food and Drug Administration in the United States.

18. Vioxx has been linked to several severe and life threatening medical disorders including, but not limited to, edema, changes in blood pressure, heart attack, stroke, seizures, kidney and liver damage, pregnancy complications and death.

19. Evidence linking the subject drug formulations to significant edema, serious cardiovascular events, and death has been noted and reported in a large study (VIGOR) that was sponsored by Merck & Company, Inc. in 2000. These known material risks were not disclosed to or shared with Plaintiffs by Defendant.

20. Defendant's strategy beginning in the 1990s has been to aggressively market and sell these products by falsely misleading potential users about the products and by failing to protect users from serious dangers which Defendant knew or should have known to result from use of these products.

21. Defendant widely and successfully marketed Vioxx in the United States by undertaking an advertising blitz extolling the virtues of Vioxx in order to induce widespread use of the products. The marketing campaign consisted of advertisements, promotional literature to be placed in the offices of doctors and other healthcare providers, and other promotional materials provided to potential Vioxx users.

22. The advertising program, as a whole, sought to create the image, impression and belief by consumers and physicians that the use of Vioxx was safe for human use, had fewer side effects and adverse reactions than other pain relief medications and would not interfere

with daily life, even though the Defendant knew these to be false, and even though the Defendant had no reasonable grounds to believe them to be true.

23. Defendant purposefully downplayed and understated the health hazards and risks associated with Vioxx. Defendant, through promotional literature, deceived potential users of Vioxx by relaying positive information, including testimonials from satisfied users, and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects. Defendant concealed materially relevant information from potential Vioxx users and minimized user and prescriber concern regarding the safety of Vioxx.

24. In particular, in the materials produced by Defendants, Defendants falsely misrepresented the severity, frequency and nature of adverse health effects caused by Vioxx, and falsely represented that adequate testing had been conducted concerning Vioxx.

25. As a result of Defendant's advertising and marketing efforts, and representations concerning the subject products, the drugs are pervasively prescribed throughout the United States.

26. On September 25, 2001, on "The Wire - News from the AP" in an article entitled "FDA Says Merck Misleading on Vioxx", a copy of which is attached as Exhibit A, it was reported as follows:

> The government has ordered Merck & Co. to cease promotions aimed to get doctors to prescribe its blockbuster arthritis painkiller Vioxx, saying they minimize potential safety risks.

The Food and Drug Administration told Merck to set the record straight by sending a "Dear Doctor" letter to all health workers who may have been exposed to the misleading campaign.

Merck has until Oct. 1 to respond.

The main issue: Whether Vioxx users face an increased risk of heart attacks and strokes. A recent study comparing Vioxx to another painkiller, naproxen, suggested they do. Many heart experts are divided about the risk and want more research. But an FDA advisory panel has said Vioxx should carry a warning label about the potential risk.

Merck has argued that Vioxx falsely looked risky because naproxen thins the blood much like aspirin does and thus protected against heart attacks. It aired that view in the recent promotions that state, "Vioxx is a wonderful, effective" painkiller but not one that has a blood-thinning side benefit.

"In fact, the situation is not at all clear," the FDA responded, saying no studies prove naproxen thins blood enough to explain the discrepancy.

"The company continues to stand behind the overall safety and cardiovascular safety of Vioxx," said Merck spokeswoman Jan Weiner.

27. In the "Warning Letter", referred to in the preceding paragraph (a copy of which has been attached as Exhibit "B") which has been made public by the FDA by posting it on its website, Thomas W. Abrams, R. Ph., MBA, Director of the Division of Drug Marketing, Advertising and Communications of the U.S. Food and Drug Administration (FDA) wrote a letter to Raymond V. Gilmartin, President and CEO of Defendant Merck & Co., Inc., regarding Vioxx (rofecoxib) tablets and alleged and stated, among other things, as follows:

> This Warning Letter concerns Merck & Co. Inc.'s (Merck) promotional activities and materials for the marketing of Vioxx (rofecoxib) tablets. . . . As part of its routine monitoring and surveillance program, the Division of Drug Marketing Advertising and Communications (DDMAC) has reviewed your promotional activities and materials and has concluded that they are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug and Cosmetic Act (the Act) and applicable regulations. See 21 U.S. C. §§ 331(a) and (b), 352(a), (f), and (n), and 355 (a).
>
> You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on

Vioxx were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparat[ive] non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).

* * *

. . . Your misrepresentation of the safety profile for Vioxx is particularly troublesome because we have previously, in an untitled letter, objected to promotional materials for Vioxx that also misrepresented Vioxx's safety profile.

* * *

We are aware of six promotional audio conferences, presented on behalf of Merck by Peter Holt, M.D. that are in violation of the Act and its implementing regulations.

* * *

The promotional audio conferences identified above, arranged by, and presented on behalf of Merck were false or misleading in that they minimized the MI results of the VIGOR study, minimized the Vioxx/Coumadin drug interaction, omitted important risk information, made unsubstantiated superiority claims, and promoted Vioxx for unapproved uses and an unapproved dosing regimen.

* * *

We have identified a Merck press release entitled, "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx," dated May 22, 2001, that is also false or misleading for similar reasons stated above. Additionally, your claim in the press release that Vioxx has a "favorable cardiovascular safety profile," is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDs is misleading; in fact, serious cardiovascular events were twice as frequent in the VIOXX treatment group (101 events, 2.5%) as in the naproxen treatment group (46 events, 1.1%) in the VIGOR study.

* * *

Merck sales representatives have engaged in false or misleading promotional activities that also minimize the potentially serious MI results observed in the VIGOR trial. . . . In addition, during the Annual Meeting of the American Society of Health Systems Pharmacists (ASHP), in Los Angeles, California, June 3 - June 6, 2001, your representative stated that Vioxx had a greater MI rate in the VIGOR trial because naproxen is cardioprotective, having platelet effects similar to aspirin. These statements made by your sales

representatives are misleading for the reasons stated above.

* * *

The promotional activities and materials described above minimize the potentially serious cardiovascular findings that were observed in the VIGOR study, minimize the Vioxx/Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for Vioxx that misrepresented Vioxx's safety profile, contained unsubstantiated comparative claims, and lacked fair balance.

Due to the seriousness of these violations, and the fact that your violative promotion of Vioxx has continued despite our prior written notification regarding similar violations, we request that you provide a detailed response to the issues raised in this Warning Letter on or before October 1, 2001. This response should contain an action plan that includes a comprehensive plan to disseminate corrective messages about the issues discussed in this letter to the audiences that received these misleading messages. This corrective action plan should also include:

1. Immediately ceasing all violative promotional activities, and the dissemination of violative promotional materials for Vioxx.

2. Issuing a "Dear Healthcare provider" letter to correct false or misleading impressions and information. This proposed letter should be submitted to us for review prior to its release. After agreement is reached on the content and audience, the letter should be disseminated by direct mail to all health care providers who were, or may have been exposed to the violative promotion.

3. A written statement of your intent to comply with "1" and "2" above.

* * *

The violations discussed in this letter do not necessarily constitute an exhaustive list. . . .

Failure to respond to this letter may result in regulatory action, including seizure or injunction, without further notice.

28. In the Journal of the American Medical Association (JAMA) for August 22-29, 2001, in an article entitled "Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors" the authors, Drs. Topol,

Nissen and Mukherjee, stated, among other things, as follows: (Article attached as Exhibit "A")

> We reviewed the cardiovascular event rates in the two major trials with selective Cox-2 inhibitors and in two smaller trials. The VIGOR trial demonstrated significantly increased risk of cardiovascular event rates with use of rofecoxib although the study enrolled patients who did not require aspirin for protection from ischemic events. Patients with angina, congestive heart failure, MI, coronary artery bypass, graft surgery within one year, stroke or transient ischemic attacks within two years, and uncontrolled hypertension were excluded from this trial.
>
> Current data would suggest that use of selective Cox-2 inhibitors might lead to increased cardiovascular events.
>
> Cox-2 inhibitors also have been shown to increase blood pressure and more patients in the VIGOR trial developed hypertension in the rofecoxib group compared with the naproxen group.
>
> Our analysis has several significant limitations. The increase in cardiovascular events in these trials was unexpected and evaluation of these endpoints was not prescribed.

> Our findings suggest a potential increase in cardiovascular event rates for the presently available Cox-2 inhibitors.
>
> Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents. Until then, we urge caution in prescribing these agents to patients at risk for cardiovascular morbidity.

29. In an article on the front page of the Wall Street Journal on August 23, 2001, entitled "Note of Caution - Study Raises Specter of Cardiovascular Risk for Hot Arthritis Pills - Vioxx and Celebrex Marketers Dispute the Research, Sought to Downplay It - A Spurned Appeal to JAMA" the authors Thomas M. Burton and Gardiner Harris stated as follows: (Article attached as Exhibit "B")

> The cardiac concerns appear in an analysis by the noted cardiologists, Eric J. Topol and Steven E. Nissen, chairman and vice chairman, respectively, of cardiovascular medicine at the Cleveland Clinic. Their study of Vioxx and Celebrex concludes, "Current data would suggest that use of these so -called 'COX-2 inhibitors' might lead to increased cardiovascular events." Their conclusions, published in today's Journal of the American Medical Association, are generally more critical of Merck's Vioxx. The authors say patients

taking Vioxx had more than twice as many heart attacks, strokes and other cardiovascular events as patients getting an older, generic arthritis drug, naproxen.

Drs. Topol and Nissen, who collaborated on the research with cardiologist Debabrata Mukherjee, now of the University of Michigan, say they have tried unsuccessfully to persuade the makers of Vioxx and Celebrex to launch new clinical studies of the possible cardiac risks. "The reluctance to move forward is disturbing," Dr. Topol says. "Either they're moving at glacial speed, or they're waiting to see what the fallout will be from this and other reports. We're staring at a major public health issue."

As FDA officials comb through all the data, say people familiar with the events, they also grew concerned about the high rate of cardiac events, especially in Merck's data on Vioxx. The agency enlisted Dr. Nissen to assist with the FDA arthritis advisory committee's evaluation of the heart data. He soon grew concerned that Merck and its own clinical investigators hadn't, in his view, sufficiently emphasized the cardiac issue. This wasn't a trifling worry. Millions of older people - those most prone to heart disease - take these arthritis drugs. So Drs. Nissen and Topol decided to air the issue. "We asked, 'What's going on here?

Are these companies being forthright?'" Dr. Topol recalls, "I wouldn't say this was buried, but the appropriate cautionary flag wasn't raised."

The largest Vioxx study analyzed by the Cleveland Clinic authors included 8,076 rheumatoid-arthritis patients treated for up to 13 months with either Vioxx or naproxen, the cheaper pill. Forty-five Vioxx patients suffered a serious, clot-related cardiac event during the study, compared with 20 in the naproxen group. These events included heart attack, unstable angina, cardiac clotting, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke and transient ischemic attacks, or ministrokes. Such events were 2.38 times as frequent in the Vioxx group as in the naproxen group.

One big reason for the drugs' popularity is marketing. In the 2001 first quarter, Celebrex and Vioxx were the second and third most heavily advertised drugs in the U.S., each with more ad dollars spent on it than Coca-Cola, according to ad-tracker CMR Inc.

30. In March 2001, in the American Journal of Therapeutics, an article entitled "Cyclooxgenase-2-Specific Inhibitors and Cardiorenal Function: A Randomized, Controlled Trial of Celecoxib and Rofecoxib in Older Hypertensive Osteoarthritis Patients," (Welton Study), the authors concluded as follows: (Article attached as Exhibit "C")

Patients taking antihypertensive therapy and receiving cyclooxygenase-2-specific inhibitors should be monitored for the development of cardiorenal events.

The authors stated as follows:

The current study was designed to understand better the cardiorenal effects of the new and widely prescribed COX-2-specific inhibitors celecoxib and rofecoxib.

* * *

Significant edema was observed in both treatment groups but occurred significantly more often in rofecoxib-treated (38 patients, 9.5%) than in celecoxib-treated patients (20 patients, 4.9%; P = 0.014).

* * *

In this study, use of COX-2-specific inhibitors was associated with cardiorenal events such as the development of edema and elevations in systolic BP. However, significantly fewer celecoxib-treated patients developed edema and elevations in systolic BP than did rofecoxib-treated patients.

* * *

Previous outcome studies in large controlled trials, such as the Systolic

Hypertension in Elderly Program and Systolic Hypertension in Europe Trial, have established that elevated systolic BP is associated with cardiovascular endpoints such as heart failure, stroke, myocardial infarction, and death.

* * *

The importance of relatively small changes to mean BP has profound public health implications. In a number of large clinical trials, sustained increases in systolic BP of 3 mmHg could explain a 10% to 20% increase in congestive heart failure, a 15% to 20% increase in stroke risk, and a 12% increase in angina risk. These findings have meaningful clinical implications for the maintenance of adequate BP control among patients with arthritis and comorbid hypertension. A small but sustained loss of adequate BP control could lead to an increase in cardiovascular events.

* * *

The effects of NSAIDs on cardiorenal function in general, and on systolic BP in particular, have important clinical implications because systolic BP is the primary modifiable factor in predicting cardiovascular risk in the elderly.

* * *

To further assess the implications of these observed differences on cardiorenal outcomes, future clinical trials with COX-2-specific inhibitors should be conducted with the addition of conventional NSAIDs and possibly placebo groups.

31. In February 2001, the Food Drug Administration (FDA) received from an FDA medical reviewer a briefing document and presentation which noted the following:

- Deaths among Vioxx-treated patients were 46% higher than naproxen-treated patients.

- Hospitalization among Vioxx-treated patients overall was some 27% greater than among naproxen-treated patients overall. Hospitalizations due to non-GI associated conditions were some 53% higher among Vioxx-treated patients.

- Vioxx-treated patients experienced a 20% higher incidence of serious adverse events overall as compared with naproxen-treated patients. Vioxx-treated patients experienced unfavorable safety comparisons in every major organ system other than the gastrointestinal system. Excluding Vioxx's GI safety

advantage, Vioxx-treated patients experienced more than a 50% higher incidence of serious adverse events.

- Serious adverse cardiovascular events are the most troublesome, with an incidence among Vioxx patients more than double that among naproxen-treated patients.

- Severe thrombotic adverse events after adjudication represent less than half of these, and heart attacks represent only 20%.

- Nevertheless, Vioxx-treated patients experienced more than twice as many thrombotic events and approximately five times as many heart attacks.

- Vioxx-treated patients experienced a higher incidence (more than double) of congestive heart failure with a greater than 93.5% probability that this difference was not random. As we said before, it is without question that congestive heart failure lowers a person's life expectancy significantly.

32. On February 7-8, 2001, Dr. Sidney M. Wolfe, M.D. and Larry Sasich, Pharm. D., MPH of the Public

Citizen Health Research Group, made a statement before the FDA's Arthritis Drugs Advisory Committee on the Nonsteroidal Anti-Inflammatory Drugs (NSAID) Celecoxib (Celebrex) and Rofecoxib (Vioxx) which included the following: (Statement attached as Exhibit "D")

> Failure of Protection from Heart Attacks and Probable Cardiac Toxicity
>
> These apparent differences in cardiac toxicity, seen in CLASS in which neither of the two comparator drugs is particularly effective, compared to aspirin, in decreasing the occurrence of heart attacks, were magnified in the rofecoxib/naproxen (VIGOR) study by the fact that naproxen, compared to either ibuprofen or diclofenac, does have a coronary protective effect similar to that of aspirin. In the discussion of the rofecoxib study, explaining the difference between naproxen and drugs such as ibuprofen and diclofenac, the authors pointed out that these latter drugs, unlike naproxen, "do not produce sustained, maximal inhibition of platelet aggregation."
>
> In that study, there was a highly statistically significant increase in heart attacks in the overall rofecoxib group (0.4%) compared to the naproxen group (0.1%). . . .
>
> Recommendations

Once again, a seemingly magic bullet appears to have self-destructed as research reveals the larger context in which it operates – the risks as well as the benefits. The benefits of COX-2 inhibitors as far as reducing GI toxicity appear to have been grossly exaggerated and oversold. Years after research on these benefits was done, a rapid accumulation of evidence on risks is occurring. For an important enzyme which is close to ubiquitous in the body, it is less than surprising that blocking its activity in one part, the gastrointestinal tract, must be balanced against the apparently harmful effects of blocking its critical functions in other parts of the body.

* * *

(2) A second box warning about cardiovascular toxicity needs to be added. It should warn of the lack of platelet aggregation inhibition of the drugs which protects those at risk from an increased occurrence of heart attacks. In addition, the evidence which is rapidly accumulating about the heart damage caused by these drugs must be mentioned in this cardiovascular box warning. We urge consultation with the cardio-renal division of FDA and, possibly with FDA's

advisory committee to accomplish this task.

33. The patient information insert on Vioxx does not fairly or adequately warn potential users of the drug with respect to an increased risk of cardiovascular events. (Vioxx advertisement which includes the insert is attached as Exhibit "E").

34. The published advertisements of Defendant Merck & Company, Inc. on Vioxx do not warn of the increased risk of serious cardiovascular events. (Advertisement attached as Exhibit "F".)

FIRST CAUSE OF ACTION

(Strict Liability - Failure to Warn - Defendant Merck & Company, Inc.)

35. Plaintiffs incorporate by reference herein Paragraphs 1 through 34 as though fully set forth herein.

36. The drug product previously described was defective as the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution, in that, and not by way of limitation, said products and their warnings, instructions and directions failed to warn of the dangerous propensities of said products, which risks were known or reasonably scientifically knowable to Defendant. The Defendant knew or should have known of the defective condition, characteristics and risks associated with said products, as previously set forth herein.

37. At all times noted herein, the aforementioned product was defective and Defendant knew that the product was to be used by the user without inspection for defects therein. Moreover, Plaintiffs neither knew, nor had reason to know at the time of the use of the subject products, of the existence of the aforementioned defects.

38. As a result of the defective condition of the aforementioned product, Plaintiffs suffered injuries and damages as alleged herein.

SECOND CAUSE OF ACTION

(Negligence - Defendant Merck & Company, Inc.)

39. Plaintiffs incorporate by reference herein Paragraphs 1 through 38 as though fully set forth herein.

40. At all times herein mentioned, Defendant had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe and adequately warn of the risks and dangers of the aforementioned product.

41. At all times herein mentioned, Defendant negligently and carelessly manufactured, designed, formulated, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold the aforementioned products and failed to adequately test and warn of the risks an dangers of the aforementioned products.

42. As a result of said negligence and carelessness of the Defendant, Plaintiff suffered injuries and damages as alleged herein.

THIRD CAUSE OF ACTION

(Violation of Law – Merck & Company, Inc)

43. Plaintiffs incorporate by reference herein Paragraphs 1 through 42 as tough fully set forth herein.

44. At all times herein mentioned, Defendant had an obligation not to violate the law, in the manufacture, design, formulation, compounding, testing, production, processing, assembly, inspection, research, distribution, marketing, labeling, packaging, preparation for use, sale and warning of the risks and dangers of the aforementioned products.

45. At all times herein mentioned, Defendant violated the Federal Food, Drug and Cosmetic Act 21 U.S.C. Section 301, et seq., including but not limited to, §§ 331(a) and (b), 352(a)(f) and (n) and 355(a), related amendments and codes and federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law.

46. Plaintiffs, as a purchaser and consumer of the products, are within the class of persons the statutes and regulations described above are designed to protect, and Plaintiffs' injuries are the type of harm these statutes are designed to prevent.

47. Defendant failed to meet the standard of care set by the following statutes and regulations, which were intended for the benefit of individuals such as Plaintiffs, making Defendants liable to Plaintiffs for the following reasons:

(a) The labeling lacked adequate information on the use of Vioxx, even though the Defendant was aware

of the widespread use of the Vioxx. [21 C.F.R. Section 201.56(a) and (d)]

(b) The labeling lacked adequate information on the approximate kind, degree and duration of expected improvement, alone or in combination in violation of 21 C.F.R. Section 201.57(c)(3)(I).

(c) The labeling failed to add warnings for serious cardiovascular events and death as soon as there was reasonable evidence of their association with the drug. [21 C.F.R. 201.57(e)]

(d) The labeling failed to add warnings for serious cardiovascular events and death as soon as there was reasonable evidence of their association with the drug. [21 C.F.R 201.57(e)]

(e) There was inadequate information for patients for the safe and effective use of Defendant's drugs, in violation of 21 C.F.R. 201.57(f)(2).

(f) There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Defendant's drugs in violation of 21 C.F.R. 201.57(f)(1).

(g) The labeling was misleading and promotion violation of 21 C.F.R. 201.56(b).

48. As a result of the violations of the statutes described above, Plaintiffs suffered injuries and damages as alleged herein.

FOURTH CASE OF ACTION

(Breach of Implied Warranty – Merck & Company, Inc.)

49. Plaintiffs incorporate by reference herein Paragraphs 1 through 48 as though fully set forth herein.

50. Prior to the time that the aforementioned products were used by Plaintiff, Defendant impliedly warranted to Plaintiffs and Plaintiffs' agents and physicians that said products were of merchantable quality and safe and fit for the use for which they were intended.

51. Plaintiffs were and are unskilled in the research, design and manufacture of the aforementioned products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendant in using the aforementioned products.

52. The aforementioned products were neither safe for their intended use nor of merchantable quality, as warranted by Defendant, in that they had dangerous propensities when put to their intended use and would cause sever injuries to the user.

53. As a result of the aforementioned breach of implied warranties by the Defendant, Plaintiffs suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION

(Breach of Express Warranty – Merck & Company, Inc.)

54. Plaintiff incorporates by reference herein Paragraphs 1 through 53 as though fully set forth herein.

55. At all times herein mentioned, Defendant expressly warranted to Plaintiffs and Plaintiffs' agents and physicians, by and through statements made by Defendant or its authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public that the aforementioned products were safe, effective, fit and proper for their intended use.

56. In utilizing the aforementioned products, Plaintiffs relied on the skill, judgment, representations and foregoing express warranties of the Defendant. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.

57. As a result of the foregoing breach of express warranties by the Defendant, Plaintiff suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION

(Negligent Misrepresentation Defendant Merck & Company, Inc.)

58. Plaintiff incorporates by reference herein Paragraphs 1 through 57 as though fully set forth herein.

59. Defendant, from the time that the aforementioned products were first manufactured, marketed and distributed, and up to the present, made false misrepresentations, as previously set forth herein, to Plaintiffs, Plaintiffs' physicians and the general public, including but not limited to the misrepresentation that said pharmaceutical product was safe, fit and effective for human consumption. At all times herein mentioned, Defendant conducted a sales and marketing campaign to promote the sale of the aforementioned drug products and willfully deceive Plaintiffs, Plaintiffs' physicians and the general public as to the health risks and consequences of the use of the aforementioned products.

60. The Defendant made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendant, by sales representatives and other authorized agents of said Defendant, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject products.

61. The foregoing representations by the Defendant, were in fact false, in that the aforementioned products were not same, fit and effective for human consumption, the use of said products is hazardous to

health, and said products have a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff as delineated herein.

62. The foregoing representations by Defendant were made with the intention of inducing reliance and the prescription, purchase and use of the subject products.

63. In reliance on the misrepresentations by the Defendant, Plaintiffs were induced to purchase and use the use of the aforementioned products. If Plaintiffs had known of the true facts and the facts concealed by the Defendant, Plaintiffs would not have used the subject products. The reliance of Plaintiffs upon Defendant's misrepresentations was justified because such misrepresentations were made an conducted by individuals and entities who were in a position to know the true facts.

64. As a result of the foregoing negligent misrepresentations by the Defendant, and each of them, Plaintiffs suffered injuries and damage as alleged herein.

SEVENTH CAUSE OF ACTION

(Fraud and Deceit - Defendant Merck & Company, Inc.)

65. Plaintiffs incorporate be reference herein Paragraphs 1 through 64 as though fully set forth herein.

66. Defendant, from the time that the aforementioned products were first manufactured, marketed and distributed, and up to the present, willfully misrepresented, omitted material facts and deceived Plaintiffs by concealing from the Plaintiff,

Plaintiffs' physicians and the general public, the true facts concerning said pharmaceutical products, which the Defendant, as manufacturer, marker and distributor of the products, had a duty to disclose.

67. Defendant Merck & Company, Inc. received letters from the Department of Health and Human Services in December of 1999 stating that it had been determined that the promotional pieces utilized by Defendant Merck & Company, Inc. were false and misleading because they contained misrepresentations of Vioxx's safety profile, unsubstantiated comparative claims, and were lacking in fair balance.

68. At all times herein mentioned, Defendant conducted a sales and marketing campaign to promote the sale of Vioxx and willfully deceive Plaintiffs, Plaintiffs' physicians and the general public as to the health risks and consequences of the use of Vioxx. Defendant was aware of the foregoing, and that Vioxx was not fit and effective for human consumption, the use of Vioxx was hazardous to health, and Vioxx had a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiffs.

69. The Defendant intentionally misrepresented and omitted material facts, and concealed and suppressed the true facts concerning Vioxx with the intent to defraud Plaintiffs, in that the Defendants knew that Plaintiffs' physicians would not prescribe Vioxx and Plaintiffs would not have used the Vioxx if they were aware of the true facts concerning the dangers of Vioxx.

70. The Defendant made the above representations, which were untrue and known to be untrue by Defendant or recklessly made such misrepresentations, omitted material facts, knowing they were material, concerning the increased risks of serious cardiovascular events; the misrepresentations and omissions of material fact were done by Defendant with intent to deceive potential users of Vioxx, including Plaintiffs, which was done for the purpose of having potential users of Vioxx, including Plaintiffs, act upon the misleading information or lack thereof, and Plaintiffs did in fact, rely on such misrepresentations or omissions by Defendant and Plaintiffs were induced thereby to act thereon in taking Vioxx which caused Plaintiffs' injury and damage.

71. As a result of the foregoing wilful, intentional, fraudulent misrepresentations, omissions of material fact and deceitful conduct by the Defendant, Plaintiffs suffered injuries and damages as alleged herein and are entitled to punitive damages from Defendant.

EIGHTH CAUSE OF ACTION

(Violation of Utah Consumer Sales Practice Act - Defendant Merck & Company, Inc.)

72. Plaintiffs incorporate and reference herein Paragraphs 1 though 71 as though fully set forth herein.

73. Plaintiffs bring this cause of action pursuant to Utah Consumer Sales Practices Act and respectfully request that the Court award all appropriate remedies provided in the prayer.

74. The Utah Consumer Sales Practices Act provides as follows:

> This act shall be construed liberally to promote the following policies:
>
> * * *
>
> (1) protect consumers from suppliers who commit deceptive and unconscionable sales practices;

(13-11-2)

> * * *
>
> (1) A deceptive act or practice by a supplier in connection with a consumer transaction violates this chapter whether it occurs before, during, or after the transaction..
>
> (2) Without limiting the scope of Subsection (1), a supplier commits a deceptive act or practice if the supplier knowingly or intentionally:
>
> (a) indicates that the subject of a consumer transaetion has sponsorship, approval, performance, characteristics, accessories, uses or benefits, if it has not;

(13-11-4)

> * * *

(3) In determining whether an act or practice is unconscionable, the court shall consider circumstances which the supplier knew or had reason to know.

(13-11-5)

* * *

(1) Whether he seeks or is entitled to damages or otherwise has an adequate remedy at law, a consumer may bring an action to:

1. obtain a declaratory judgment that an act or practice violates this chapter; and
2. enjoin, in accordance with the principles of equity, a supplier who has violated, is violating, or is likely to violate this chapter.

(2) A consumer who suffers loss as a result of a violation of this chapter may recover, but not in a class action, actual damages or $2,000, whichever is greater, plus court costs.

(13-11-19)

75. The acts and practices described in Paragraphs 1 through 68 above constitute a deceptive act or practice and/or an unconscionable act or practice

by Defendant and thus violates the Utah Consumer Sales Practice Act, in the following particulars, among others:

(a) Representing to Plaintiffs, Plaintiffs' physicians and the general public that Vioxx was safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the Plaintiffs, Plaintiffs' physicians and the general public that said products had a serious propensity to cause injuries to users;

(b) Engaging in advertising programs designed to create the image, impression and belief by consumers, physicians that the use of Vioxx was safe for human use, had fewer side effects and adverse reactions than other pain medication, constituted a convenient, safe form of pain relief and would not interfere with daily life, even though the Defendant knew these to be false, and even though the Defendant had no reasonable grounds to believe them to be true;

(c) Purposely downplaying and understating the health hazards and risks associated with Vioxx;

(d) Issuing promotional literature deceiving potential users of Vioxx by relaying positive information, including testimonials from satisfied users, and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety of said products.

76. The violation of the Utah Consumers Sales Practices Act by Defendant, as described above, represents a continuing threat to members of the public in that Defendant continues to engage in the conduct described therein.

77. Plaintiffs, pursuant to the Utah Consumer Sales Practices Act, seek an order of this court that the acts or practices of the Defendant violate this law and Defendant is enjoined, in accordance with the principles of equity, from violating this law, and, further, that Plaintiffs are entitled to their actual damages or $2,000, whichever is greater, plus court costs.

WHEREFORE, Plaintiff prays for judgment against Defendant Merck & Company, Inc. as follows:

1. For past and future general damages, according to proof;

2. For past and future medical and incidental expenses, according to proof;

3. For past and future loss of earnings and/or earning capacity, according to proof;

4. For punitive and exemplary damages in an amount to be determined at trial;

5. For prejudgment interest on all damages as is allowed by the laws of the State of Utah;

6. For past and future mental and emotional distress, according to proof;

7. For past and future loss of consortium, according to proof;

8. For past and future costs of suit incurred herein;

9. For injunctive relief, enjoining Defendant from violating the Utah Consumer Sales Practices Act.

10. For such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury and submits the statutory fee herewith.

DATED this 28th day of September, 2001

MORGAN, MYER & RICE, L.C.

/S/ STEPHEN G. MORGAN

STEPHEN G. MORGAN
CYNTHIA K.C. MEYER
MITCHEL T. RICE
JOSEPH E. MINNOCK
ATTORNEYS FOR PLAINTIFFS

IN THE CIRCUIT COURT OF
MARION COUNTY, ALABAMA

Case No. CV-01-193
Filed October 1, 2001

JAMES ROGER HOLCOMB, PLAINTIFF

v.

DR. RAJ K. SEHGAL; CARRAWAY METHODIST HEALTH SYSTEMS, INC. D/B/A CARRAWAY NORTHWEST MEDICAL CENTER; CARRAWAY NORTHWEST MEDICAL CENTER, INDIVIDUALLY; UNKNOWN PHYSICIANS A, B, C, D AND E WHO READ STUDIES, TOOK HISTORIES, EXAMINED OR OTHERWISE PROVIDED CLINICAL OR DIAGNOSTIC CARE TO JAMES HOLCOMB ON SEPTEMBER 19TH AND 20TH, 1999, AT CARRAWAY NORTHWEST MEDICAL CENTER AND FAILED TO ORDER PROPER TESTS OR PROVIDE PROPER CARE; AND MERCK & CO., INC., DEFENDANTS

COMPLAINT
JURISDICTION & VENUE

1.

James Roger Holcomb is an adult resident citizen of Lamar County, Alabama, and has been for more than one year preceding.

2.

Dr. Raj H. Sehgal is a physician found doing business in Marion County, Winfield, Alabama, and is an adult resident citizen of same county and has been for

more than one year preceding. He can be served with process at his place of business, 2685 US Highway 43, Winfield, AL 35594.

3.

Carraway Methodist Health Systems d/b/a Carraway Northwest Medical Center is a corporation found doing business in Marion County, Winfield, Alabama, and has been for more than one year preceding. It can be served through its chairman of the board and chief executive officer, Robert P. Carraway, M.D. at Carraway Methodist Health Systems, 1600 Carraway Boulevard, Birmingham, AL 35234. Carraway Northwest Medical Center, individually, may be served through its Administrator at the Winfield facility or through Dr. Robert P. Carraway as noted above. Carraway Northwest Medical Center is part of Carraway Methodist Health Systems.

4.

Unknown physicians A, B, C, D and E who took histories, read studies and otherwise diagnosed and/or treated James Roger Holcomb at or through Carraway Northwest Medical Center in Marion County, Alabama, on or about Setpember 19th and 20th, 1999.

5.

Merck & Co., Inc., is a foreign corporation found doing business in Alabama who may be served with process throught its chariman, president and chief executive officer, Raymond V. Gilmartin, at Merck & Co., Inc., One Merck Drive, Post Office Box 100, Whitehouse Station, N.J 08889-0100.

COUNT 1: MEDICAL MALPRACTICE

6.

Mr. Holcomb began experiencing chest pains during the period between September 17th and 19th, 1999, while in Gulf Shores, Alabama. Upon his return to Marion County, he went to the Emergency Room at Carraway Northwest Medical Center complaining of chest pains.

7.

While at Carraway Northwest Medical Center, certain tests, including EKG's and blood enzymes were performed. Those who read them erroneously reported them as negative. The physicians who read the tests and the follow-up tests of the EKG failed to note the wave forms and/or failed to notify Mr. Holcomb of the impending heart attack shown by the EKG's.

8.

The clinical tests done; the history taken; and other diagnostic tools as applied by the various physicians were misinterpreted by Dr. Sehgal who saw Mr. Holcomb in the hospital on September 19th and 20th and the other physicians who saw the test results. Those who interpreted the tests or otherwsie aided in the care of Mr. Holcomb during this period failed to properly diagnose and treat the chest pains with the clinical picture as presented. The tests were improperly done by the above.

9.

Mr. Holcomb was erroneously discharged from the hospital by these same physicians, including Dr. Sehgal, who indicated that he only had indigestion and

prescribed Pepsid AC. He was told to report to Dr. Sehgal on September 29, 1999.

10.

Mr. Holcomb did see Dr. Sehgal on September 29, 1999. Dr. Sehgal told him again that he only had indigestion based on Dr. Sehgal's own observations, on tests, history, and the other materials that he had on hand, as well as, information from A, B, C, D and E as noted above. Dr. Sehgal failed to take into account the EKG's. Alternatively, interpretations of other physicians which indicated that Mr. Holcomb was in danger and did, indeed, experience heart problems were ignored by Dr. Sehgal. On September 29, 1999, Dr. Sehgal erroneously told Mr. Holcomb that he had no problems and to continue to take Pepsid AC and discharged him to home.

11.

Three days later, on October 1, 1999, Mr. Holcomb suffered a heart attack while shopping at Wal-Mart in Amory, Mississippi. He survived only because the Wal-Mart was near Gilmore Memorial Hospital in Amory and he was rushed, quickly, across the street to the hospital where he was stabilized.

12.

He was later transferred to North Mississippi Medical Center in Tupelo, Mississippi, where tests disclosed that he had a major blockage of a major artery of his heart. This blockage existed at the time Mr. Holcomb was in Carraway Northwest as well as when he saw Dr. Sehgal in his office, and Dr. Sehgal and others told Mr. Holcomb that his chest pains were indigestion. They were not signs and symptoms of indigestion; they were caused by a blockage of a major cardiac artery.

13.

As a result of the delay in treatment, Mr. Holcomb suffered significant and permanent damage to his heart. The heart muscles are weaker than they were and the ejection fraction is lower. The heart cannot pump blood well. As a result of the heart attack, Mr. Holcomb is weaker; his activities are limited; he has lost and will lose income; he is in danger of further heart attacks; and he has lost life expectancy due to this damage. Mr. Holcomb has incurred medical costs and associated costs, past, present and future.

14.

This damage was entirely avoidable. The blockage was removed by a stint at North Mississippi Medical Center. This could have been done earlier, without damage, if Dr. Sehgal had ordered the proper tests or if the unknown doctors A, B, C, D and E had given the information necessary to order the next level of tests which would have disclosed the blockage which would then have led to a stint which would have prevented the heart attack.

15.

Dr. Sehgal and the unknown physicians by their failure to diagnose the impending heart attack by failing to properly read the EKG's; failing to properly interpret the blood enzymes; failing to re-read and re-study those test results; failing to notify; failing to diagnose based on the totality of signs, symptoms and tests; failing to arrange the proper next level of tests, given Mr. Holcomb's condition; and instead prescribing Pepsid AC for what turned out to be a blockage of a major artery, fell below the minimum standards of care. As a result, the damages above occurred.

16.

For the extra medical bills, loss of income, loss of enjoyment of living, loss of life expectancy, loss of function of the heart and all of the associated problems of the avoidable heart attack, compensation is demanded in an amount set properly by a struck jury.

COUNT II: PRODUCTS LIABILITY FOR A DRUG CAUSING HEART ATTACK

17.

The above facts are reincorporated and re-alleged.

18.

Dr. Erich Wouters had prescribed Vioxx on September 13, 1999, to Mr. Holcomb. He had been continuing to take that from September 13, 1999, up to the time of his heart attack as presribed by Dr. Wouters and continued by Dr. Sehgal.

19.

Undisclosed to Dr. Wouters and Dr. Sehgal by Merck & Co., Inc., the manufacturer of Vioxx, Vioxx causes heart attacks. This was a matter undisclosed to the physicians so they could not take that into account as a side effect.

20.

Vioxx is a cause or proximate contributing cause of the heart attack described above and the damage described above.

21.

Merck Pharmaceutical, Inc., is liable under the following theories:

A. failure to warn the physician;

B. manufacturing a product unsafe for its intended use, given that the danger of heart attacks is not a reasonable risk to relieve the muscular and arthritic pain that it serves to relieve;

C. willful concealment of these facts from the Food an Drug Administration prior to approval and willful concealment and suppression of these facts so that the physicians would not know in order to make their decision.

22.

The drug is an unsafe product under the Alabama Extended Manufacturer's Liability Doctrine.

23.

It is an unsafe product under negligence theories as a breach of duty to the public by failure to warn and by failure to properly manufacture and design a product and failure to disclose all necessary facts rendering the product unsafe for its intended purposes.

24.

Vioxx, by suppression of facts and lack of warning, is rendered unmerchantable and not fit for its particular purposes as an item under the Uniform Commercial Code and therefore breaches implied warranties of merchantability and fitness for its particular pruposes.

25.

The damages above are re-alleged and reincorporated as there is loss of use of the heart, loss of income, loss of enjoyment of living, loss of bodily function, loss of life expectancy, mental anguish and all

other damages associated with a heart attack and damage to the heart as noted above and can reasonably be expected in the past, present and future. Compensation is demanded or these as properly determined by a struck jury.

26.

Moreover, the suppression being willful, the concealment being willful and putting the public in danger, punitive damages are justified for these willful and repeated acts and for the suppression for the purpose of profit. The profit should not be garnered for the drug and profit should be kept if that is the motivating factor and the manufacturer is willing to risk human life in order to do that. This is a willful, wanton and reckless act justifying punitive damages and is independently a wanton act and the tort of wantonness is alleged and damages for same demanded as determined by a struck jury.

RESPECTFULLY SUBMITTED, this the 1st day of October, 2001.

/S/ DENNIS HARMON
DENNIS HARMON
ATTORNEY AT LAW
517 MAIN STREET
POST OFFICE BOX 52
COLUMBUS, MS 39703
(662) 328-9365
AL BAR #HAR134

IN THE CIRCUIT COURT OF
MARION COUNTY, ALABAMA

Case No. CV-01-193
Filed October 1, 2001

JAMES ROGER HOLCOMB, PLAINTIFF
V.
DR. RAJ K. SEHGAL; CARRAWAY METHODIST HEALTH SYSTEMS, INC. D/B/A CARRAWAY NORTHWEST MEDICAL CENTER; CARRAWAY NORTHWEST MEDICAL CENTER, INDIVIDUALLY; UNKNOWN PHYSICIANS A, B, C, D AND E WHO READ STUDIES, TOOK HISTORIES, EXAMINED OR OTHERWISE PROVIDED CLINICAL OR DIAGNOSTIC CARE TO JAMES HOLCOMB ON SEPTEMBER 19TH AND 20TH, 1999, AT CARRAWAY NORTHWEST MEDICAL CENTER AND FAILED TO ORDER PROPER TESTS OR PROVIDE PROPER CARE; AND MERCK & CO., INC., DEFENDANTS

DEMAND FOR JURY TRIAL

MAY IT PLEASE THE COURT:

Plaintiff demands a jury trial by a struck jury.

RESPECTFULLY SUBMITTED, this the 1st day of October, 2001.

/S/ DENNIS HARMON
DENNIS HARMON
ATTORNEY AT LAW
517 MAIN STREET
POST OFFICE BOX 52
COLUMBUS, MS 39703
(662) 328-9365
AL BAR #HAR134

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

Case No. 01-cv- 3441

ALEX CAIN AND WILLIAM WATKINS, PLAINTIFFS

v.

MERCK & CO., INC., PHARMACIA CORPORATION, PFIZER INC. AND G.D. SEARLE & CO., DEFENDANTS

ANSWER

Defendant Merck & Co., Inc. ("Merck"), by its attorneys Hughes Hubbard & Reed LLP, answers the Amended Class Action Complaint ("Complaint") herein as follows:

1. Denies each and every allegation contained in paragraph 1 of the Complaint except admits that the named plaintiffs purport to bring this action on behalf of themselves individually and on behalf of the class of patients who have taken Vioxx or Celebrex, but denies that there is any legal or factual basis for such claims.

2. Denies each and every allegation contained in paragraph 2 of the Complaint except admits that the named plaintiffs seek "emergency notice" but denies that there is any factual or legal basis for the notice sought.

3. Denies each and every allegation contained in paragraphs 3 of the Complaint except admits that osteoarthritis is the most prevalent form of arthritis.

4. Denies each and every allegation contained in paragraph 4 of the Complaint except admits that the prevalence of osteoarthritis increases with age.

5. Denies each and every allegation contained in paragraph 5 of the Complaint except admits that Vioxx reduces pain and inflammation and that the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 ("Cox-2") and states that it lacks knowledge or information with respect to the allegations made about Celebrex in said paragraph.

6. The allegations contained in paragraphs 6 and 7 of the Complaint are not directed toward Merck and therefore no responsive pleading is required.

7. Denies each and every allegation contained in paragraph 8 of the Complaint except admits that sales of Vioxx have been substantial and further admits that Merck markets Vioxx.

8. Denies each and every allegation contained in paragraph 9 of the Complaint except admits that Vioxx has been approved by the FDA and is indicated for relief of the signs and symptoms of osteoarthritis, the management of acute pain in adults, and the treatment of primary dysmenorrhea.

9. Denies each and every allegation contained in paragraph 10 of the Complaint to the extent said allegations are directed at Merck. To the extent said allegations are directed toward others, Merck states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of such allegations.

10. Denies each and every allegation contained in paragraphs 11 through 15 of the Complaint.

11. The allegations contained in paragraph 16 of the Complaint are legal conclusion and therefore no responsive pleading is required. To the extent a response is deemed to be required, Merck denies each and every allegation contained in said paragraph except admits that plaintiffs seek emergency notice and denies that there is a legal or factual basis for such relief.

12. Denies each and every allegation contained in paragraphs 17 and 18 of the Complaint except admits that patients — in consultation with their physicians — should have the opportunity to make informed, educated choices regarding pain relief therapies.

13. States that the allegations contained in paragraph 19 of the Complaint are legal conclusions and therefore no responsive pleading is required.

14. Denies each and every allegation contained in paragraph 20 of the Complaint and states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first sentence of said paragraph.

15. Denies each and every allegation contained in paragraph 21 of the Complaint and states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first sentence of said paragraph.

16. Admits the allegation contained in paragraph 22 that Merck is incorporated in New Jersey and has its principal place of business there and that Merck does business in New York.

17. States that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraphs 23 through 25 of the Complaint.

18. The allegations contained in paragraphs 26 through 28 of the Complaint are legal conclusions and therefore no responsive pleading is required. To the extent a response is deemed to be required, Merck denies each and every allegation contained in said paragraphs.

19. The allegations contained in paragraphs 29 and 30 of the Complaint are legal conclusions and as such no responsive pleading is required. To the extent a response is deemed to be required, Merck denies each and every allegation contained in said paragraphs except admits that plaintiffs seek to bring this action as a class action and denies that there is any legal or factual basis for such claims.

20. The allegations contained in paragraphs 31 of the Complaint are legal conclusions and therefore no responsive pleading is required. To the extent a response is deemed to be required, Merck denies each and every allegation contained in said paragraphs.

21. Denies each and every allegation contained in paragraph 32 of the Complaint.

22. Denies each and every allegation contained in paragraph 33 of the Complaint except admits on information and belief that plaintiffs' counsel has participated in class actions.

23. Denies each and every allegation contained in paragraphs 34 through 36 of the Complaint.

24. With respect to the allegations contained in paragraph 37 of the Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 23 of this Answer with the same force and effect as though set forth here in full.

25. Denies each and every allegation contained in paragraphs 38 through 41 of the Complaint.

26. With respect to the allegations contained in paragraph 42 of the Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 25 of this Answer with the same force and effect as though set forth here in full.

27. Denies each and every allegation contained in paragraphs 43 through 46 of the Complaint.

28. With respect to the allegations contained in paragraph 47 of the Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 27 of this Answer with the same force and effect as though set forth here in full.

29. The allegations contained in paragraph 48 of the Complaint are legal conclusions and therefore no responsive pleading is required. To the extent a response is deemed to be required, Merck denies each and every allegation contained in said paragraph.

30. Denies each and every allegation contained in paragraphs 49 through 53 of the Complaint.

31. With respect to the allegations contained in paragraph 54 of the Complaint, repeats and realleges each and every admission, denial, averment, and

statement contained in paragraphs 1 through 30 of this Answer with the same force and effect as though set forth here in full.

32. Denies each and every allegation contained in paragraph 55 of the Complaint except admits that Vioxx is safe and effective for its indicated uses subject to the information contained in its package insert.

33. Denies each and every allegation contained in paragraph 56 of the Complaint to the extent said allegations are directed toward Merck and states that it lacks knowledge or information sufficient to form a belief as to the truth or falsity of said allegations to the extent said allegations are directed toward others.

34. Denies each and every allegation contained in paragraph 57 of the Complaint.

35. With respect to the allegations contained in paragraph 58 of the Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 34 of this Answer with the same force and effect as though set forth here in full.

36. Denies each and every allegation contained in paragraph 59 of the Complaint except admits that Vioxx is safe and effective for its indicated uses subject to the information contained in its package insert.

37. Denies each and every allegation contained in paragraphs 60 and 61 of the Complaint.

38. The allegations contained in paragraph 62 of the Complaint are legal conclusions and therefore no responsive pleading is required. To the extent a response is deemed to be required, Merck denies each and every allegation contained in said paragraph

39. With respect to the allegations contained in paragraph 63 of the Complaint, repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 39 of this Answer with the same force and effect as though set forth here in full.

40. The allegations contained in paragraphs 64 and 65 of the Complaint are legal conclusions and as such no responsive pleading is required. To the extent a response is deemed to be required, Merck denies each and every allegation contained in said paragraphs except admits that studies have been conducted regarding Vioxx.

41. Denies each and every allegation contained in paragraph 66 of the Complaint.

42. The allegations contained in paragraphs 67 and 68 of the Complaint are legal conclusions and therefore no responsive pleading is required. To the extent a response is deemed to be required, Merck denies each and every allegation contained in said paragraph.

AS FOR A FIRST
DEFENSE, MERCK ALLEGES:

43. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

AS FOR A SECOND
DEFENSE, MERCK ALLEGES:

44. The Complaint fails to state a claim upon which relief can be granted.

AS FOR A THIRD DEFENSE, MERCK ALLEGES:

45. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

AS FOR A FOURTH DEFENSE, MERCK ALLEGES:

46. If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or loses were caused in whole or in part through the operation of nature or other intervening cause or causes.

AS FOR A FIFTH DEFENSE, MERCK ALLEGES:

47. To the extent that plaintiffs assert claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

AS FOR A SIXTH DEFENSE, MERCK ALLEGES:

48. To the extent that plaintiffs assert claims in the Complaint based upon an alleged failure by Merck to warn plaintiffs directly of alleged dangers associated with the use of Vioxx, such claims are barred because Merck has discharged its duty to warn in its warnings to the prescribing physician.

AS FOR A SEVENTH DEFENSE, MERCK ALLEGES:

49. Each and every claim asserted or raised in the Complaint is barred by the doctrines of accord and satisfaction, res judicata, payment and release.

AS FOR AN EIGHTH DEFENSE, MERCK ALLEGES:

50. If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured plaintiffs.

AS FOR A NINTH DEFENSE, MERCK ALLEGES:

51. If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or by some other defendant named herein allegedly ingested or administered.

AS FOR A TENTH DEFENSE, MERCK ALLEGES:

52. If plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

AS FOR AN ELEVENTH DEFENSE, MERCK ALLEGES:

53. If plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by plaintiffs' misuse or abuse of Vioxx.

AS FOR A TWELFTH DEFENSE, MERCK ALLEGES:

54. If plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses.

AS FOR A THIRTEENTH DEFENSE, MERCK ALLEGES:

55. Plaintiffs' claims are barred in whole or in part because Vioxx is a prescription medication which is "unavoidably unsafe" within the meaning of comment k to Section 402A of the Restatement (Second) of Torts.

AS FOR A FOURTEENTH DEFENSE, MERCK ALLEGES:

56. Plaintiffs claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

AS FOR A FIFTEENTH DEFENSE, MERCK ALLEGES:

57. To the extent that plaintiffs rely upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

AS FOR A SIXTEENTH DEFENSE, MERCK ALLEGES:

58. To the extent plaintiffs have settled or will in the future settle with any defendants or any other person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

AS FOR A SEVENTEENTH DEFENSE, MERCK ALLEGES:

59. To the extent that plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

AS FOR AN EIGHTEENTH DEFENSE, MERCK ALLEGES:

60. Plaintiffs' claims for strict liability and breach of warranty are barred on the grounds that such claims are not cognizable against Merck.

AS FOR A NINETEENTH DEFENSE, MERCK ALLEGES:

61. To the extent plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the

Complaint, such benefits are not recoverable in this action under the applicable state law

AS FOR A TWENTIETH DEFENSE, MERCK ALLEGES:

62. Plaintiffs' demand for punitive damages is barred under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. §301.

AS FOR A TWENTY-FIRST DEFENSE, MERCK ALLEGES:

63. Plaintiffs' claims are barred in whole or in part of the First Amendment.

AS FOR A TWENTY-SECOND DEFENSE, MERCK ALLEGES:

64. Plaintiffs' claims for injunctive relief are barred by the doctrine of primary jurisdiction.

AS FOR A TWENTY-THIRD DEFENSE, MERCK ALLEGES:

65. Plaintiffs' claims are barred, in whole or in part, because plaintiffs lack standing to bring such claims.

Merck incorporates by reference and makes a part hereof all other applicable affirmative defenses set forth in the answers of any other defendant and will rely on all defenses which may become available during discovery or trial.

WHEREFORE, Merck demands judgment dismissing plaintiffs' Complaint and awarding Merck its fees and costs, together with such other and further relief that the Court may deem just and proper.

Dated: New York, New York
September __, 2001

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MDL No. 1658

Case No. 05-cv-2367 (SRC)

IN RE: MERCK & CO., INC. SECURITIES, DERIVATIVE & "ERISA" LITIGATION

HEARING ON MOTION TO DISMISS
March 26, 2007

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THE CLERK: Counsel on Merck, there was an appearance sheet that was circulated.

THE COURT: All right. Can I have appearances by counsel please.

MR. CECCHI: James Cecchi, Carella Byrne, on behalf of the plaintiffs. Mr. Weiss will be here momentarily. I think he went to the men's room.

MR. BROWER: David Brower, Brower Pivin. Good morning, your Honor.

MR. COFFEY: Sean Coffey from Bernstein Litowitz on behalf of Mississippi.

MR. CHESLER: Good morning. Evan Chesler on behalf of Merck and Karen King from my office is with me.

MR. STEIN: William Stein on behalf of Merck.

MR. PERSCHETZ: Good morning, your Honor. Martin Perschetz on behalf of defendant Edward Scolnick.

MS. SADIGHI: Sheila Sadighi, Lowensetein Sandler, on behalf of defendant Edward Scolnick.

MR. WEISS: Melvyn Weiss of Milberg Weiss on behalf of the plaintiffs.

THE COURT: Good morning to all of you. Mr. Chesler, glad to see that you've had an opportunity to get a break in your schedule. Have you been on nonstop trial?

MR. CHESLER: I have, your Honor. Thank you very much for accommodating that schedule. I very much appreciate it.

THE COURT: All right. If we have everybody here, Mr. Chesler, it's your application.

MR. CHESLER: Yes, your Honor.

THE COURT: I'll hear you.

MR. CHESLER: Thank you, your Honor. As I'm sure your Honor knows, this is a lawsuit about whether

or not my client misled the market about the cardiovascular risk associated with taking Vioxx, alleged cardiovascular risk. The plaintiffs' contention is that we did mislead the market, that they, therefore, bought their shares at inflated prices and their allegation is that when the truth about that risk was disclosed, share price fell and that they were injured as a result of that.

We have moved to dismiss on a number of grounds which I'm sure your Honor is familiar with. They're set forth in the papers. I'm going to focus on one issue which actually cuts across at least three or four of the legal grounds and it seems to me, your Honor, that for efficiency purposes, since I believe that is clearly a dispositive ground and supports, as I say, three or four different legal grounds that are asserted in the briefs, I'm going to spend my time if I may focused on that and, that is, was the market in fact adequately informed of the alleged risk of cardiovascular incidents from taking the drug, because if it was, then this lawsuit is plainly untimely. It is plainly the case that there cannot be fraud-on-the-market reliance because truth was on the market. It was plainly the case that there cannot have been actionable statements or omissions because the same information was available to investors and the '33 Act claims would fall as well, so, that's what I'm going to focus on.

I want to begin that piece, your Honor, by emphasizing, and I won't keep repeating it, that of course Merck's position is that it is not liable to anyone for any alleged injury from having taken the drug and, as your Honor I'm sure knows, there are multiple product liability cases, many of which have been tried, many more remain to be tried.

That is not the issue with respect to our application today. As I said at the outset, the issue today is whether

or not the market was adequately apprised of that alleged risk because if it was, if there were, in the words of the Third Circuit, storm warnings available to the plaintiffs, then the clock for their filing this lawsuit began to run long before they filed and, indeed, more than two years before they filed which, as a matter of law, would render this lawsuit untimely.

As I think, your Honor, the record before you on this motion which of course is based upon the pleading but also upon matters which your Honor has previously indicated are appropriate because they are referred to in the complaint and your Honor's entitled to see the full text before you, the disclosures here are massive. We're talking about literally hundreds of publications, hundreds of articles and a debate that went on among the scientific community and was widely recorded both in the technical press and in the general press about this question of cardiovascular risk and, in particular, your Honor, in March of 2000 there was a study known as the VIGOR study which was publicly disclosed. Debate followed.

In February of 2001 there was a public hearing by the FDA Advisory Committee with respect to arthritis. The debate thereafter continued. Beginning in May of 2001, there were product liability class actions, and I will come back to those, the first of which was filed on May 29th, alleging that precisely the risk which these plaintiffs claim was not adequately communicated to the market, precisely that risk was alleged in multiple class action complaints beginning in May of 2001, as having been the cause of alleged injury to the members of those classes who claim cardiovascular disease resulting from taking Vioxx.

There was a very well publicized and broadly debated and discussed article in August of 2001 from the Journal

of the American Medical Association discussing again the very same risk and there was in mid-September of 2001 -- and this is one of the critical disclosures I'll come back to -- a public warning letter from the FDA, the text of which is critical to this application, and I will come back to it, and in the days following that warning letter, within 10 days in fact of the publication of that warning letter, which was on September 17th, there were three more product liability class actions filed by three different law firms in New Jersey, in Salt Lake, Utah and in Alabama, so, more than two years --

THE COURT: Was Utah a class action? I thought it was a multi-plaintiff but it was not a class action.

MR. CHESLER: You're right, it was multi-plaintiff. Four lawsuits, four lawsuits alleging exactly the same risk of cardiovascular disease on behalf of people allegedly injured from taking Vioxx more than two years before the first of the securities class actions was filed in early November of 2003.

The legal standard, as I'm sure your Honor is aware, is pretty clearly set forth in the Third Circuit in the NAHC and in the Benak cases, and as the Benak court said last year, if there is sufficient information of possible wrongdoing to place the plaintiffs on inquiry notice or to excite storm warnings of culpable activity, the burden then shifts to the plaintiffs to demonstrate that they conducted an appropriate investigation and were unable to find a basis for their claim.

Here there is, I don't believe, any contest that no such investigation was in fact conducted. There is none alleged. The storm warnings took place long before the statutory period and we believe under Benak the case must be dismissed and critically, your Honor, in the Benak case, the Third Circuit relied very squarely on the fact, and that case, of course, it was before the two year,

the length in two-year statute of limitations was put into effect under Sarbanes, so, it was a one-year statute in that case.

In the Benak case the Third Circuit made quite clear that the fact that a prior lawsuit was filed that alleged essentially the same fraud more than one year before the securities case in Benak was dispositive and the court relied upon that very heavily to find that the Benak case was untimely.

With respect to the specific disclosures, I want to focus, although we could spend all day talking about them, as your Honor knows, it's a big pile of disclosures, but I want to focus on just two categories, and there are only five of them altogether and I'm going to go through them very quickly.

The first is the product liability losses. Now, on May 23rd, 2001, two and a half years before the first of the securities cases was filed, my old friend David Boies filed a lawsuit in the Eastern District of New York federal court on behalf of the class allegedly injured from taking Vioxx and in that complaint filed in May of '01, paragraph three says, quote, As demonstrated by Merck's own research, users of Vioxx were four times as likely to suffer heart attacks as compared to other less expensive medications or combinations thereof. And in paragraph 29 he alleges, Vioxx is unaccompanied by adequate warnings regarding the higher risk of heart attacks.

Now, several months following those allegations he had no problem satisfying Rule 11 requirements, let alone the much lower threshold of when the statute begins to run under the Benak standard. But several months later in the FDA warning letter, your Honor, on September 17th, the FDA said among other things, quote, You have engaged -- you being Merck -- You have

engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the VIGOR study. The campaign, quote, misrepresents the safety profile for Vioxx. They said, You failed to disclose that your explanation is hypothetical and that there is another reasonable explanation that Vioxx may have pro-thrombotic properties and you minimize the Vioxx myocardial infarction rate observed in the VIGOR study.

I would ask your Honor to consider this. In the Benak case which, of course, was the purchasers of a mutual fund that had in turn purchased shares of Enron and the question is whether the lawsuit against that mutual fund was timely or not and, of course, the Third Circuit found it was untimely, relying among other things but particularly on a prior fraud case that was filed more than a year before. I would ask your Honor to consider this in the context of the FDA warning letter in our case. The regulatory equivalent of that FDA warning letter in the Benak case would have been a public warning by the SEC saying you have misrepresented the financial condition of Enron.

Just consider, your Honor, what the Third Circuit would have done with that, given that they found the case untimely on the record before them anyway. Imagine if more than a year before that lawsuit had been filed in the district court the SEC had said publicly, accused the Enron folks of misrepresenting their financial condition, whether the Third Circuit would have had any trouble finding in the wake of that disclosure that the case was untimely.

Here the question is whether the market was adequately apprised that there was an alleged safety profile issue, a risk of cardiovascular disease from taking Vioxx, the failure to disclose which allegedly inflated the

stock price. The FDA said 26 months before the plaintiffs filed this lawsuit that we had misrepresented precisely that safety profile, and within 10 days of that warning letter, as I said before, four other product liability cases were filed.

In the Astin case, which was filed in New Jersey on September 27th, the complaint cites the FDA warning letter as grounds to support its allegation that their clients had been injured and that that risk had not been adequately disclosed before that time. They also cite an August 22nd Wall Street Journal article that, quote, questions -- that said questions existed about the safety and efficacy of Vioxx.

The next day the Utah action is filed and it begins in the first paragraph and it says, Vioxx causes serious medical problems such as an increased risk of cardiovascular events, including strokes, heart attacks and death. It cites the FDA warning letter. It cites a September 25th AP story, an August 1st JAMA article, an August 23rd Wall Street Journal article, and a pile of others, all of which are before this Court.

The Holcomb case in Alabama on October 1st, paragraph 19 says, Vioxx causes heart attacks. And Mr. Boies and his colleagues and the plaintiffs' bar in the product liability cases apparently had no trouble figuring out the alleged risk.

It is only the securities plaintiffs who seem to have been in the cave somewhere unaware of this public debate. Your Honor, the simple truth is they waited too long. When the FDA says publicly that we misrepresented the safety profile, that's not a storm warning, it's a tsunami. And they sat on their rights and they didn't do anything and they're trying now to rehabilitate that mistake by making two arguments, neither of which passes any muster.

The first argument is we didn't disclose some of the clinical data. First of all, that's untrue, and we've put before your Honor all of the evidence which is appropriate on a motion to dismiss because it's all averted to in the complaint. The 090 study, Exhibit 2, demonstrates the data were put before the FDA and published -- publicly known in February of '01. The Advantage or 102 studies, Exhibit 7, makes clear that by July of '01, it was publicly disclosed that there had been five reported heart attacks and two related deaths, and a month later, a couple months later that was updated to three.

The VIGOR study, their own exhibit, your Honor, their own plaintiff's Exhibit 46 says, quote, this is a New England Journal of Medicine article, quote, The editors first became aware of the additional MIs in 2001, when updated data were made public by the FDA. Their own exhibit admits that the VIGOR study was publicly known. And in the FDA warning letter, which is Exhibit 1 to our papers, at page two the FDA said in September of 2001, more than two years before they filed their lawsuit, quote, These unexpected findings, referring specifically to the higher cardiovascular reported results in the VIGOR study, were, quote, extensively discussed at the FDA arthritis advisory committee meeting on February 8, 2001.

So, with respect to the plaintiffs' strategy to argue that they should somehow be forgiven for their late filing because some clinical data were not in fact disclosed in a timely fashion, it is untrue. It is untrue. And even if it were true, your Honor, the FDA warning letter was 26 months before the complaint. The product liability cases were two and a half years to 25 months before the complaint. None of those people, including the FDA, had any problem identifying this alleged risk and the

plaintiffs say that they're excused because the data were not complete. That argument simply doesn't fly.

The other strategy of avoidance is that Merck has maintained, as I said at the beginning of my remarks, throughout that it is not in fact liable for any alleged safety risks involving Vioxx, and that somehow their failure to observe the storm warnings should be excused because Vioxx proceed -- Merck protests its innocence.

Well, your Honor, as many cases have said and we quoted in our papers, if that argument were right, then defendants, in order to win a statute of limitations argument, would have to concede liability if they dare to protest, if they dare to protest their innocence, if they dare to argue the facts which actually cut their way, in this case the debate on whether Naproxen actually helped people or Vioxx hurt people, then you're deprived of an argument that the market was adequately informed of the risk. That's not what Judge Wolfson said in the Exxon case in this district. He held exactly to the contrary and, in fact, your Honor, the most telling evidence that that argument doesn't work here is the fact that these plaintiffs filed their first lawsuit on September 6 of 2001, in the face of exactly those protestations of innocence. Why wasn't it enough to prevent them from filing then but it's enough to excuse their untimely filing now?

And if you look at that complaint in September of '01, you look at what the trigger was, remember, they claim the FDA warning letter misrepresenting the safety profile wasn't enough, allegedly minimizing the evidence wasn't enough. What did they allege in that complaint was enough? Paragraph 54, this is of the September 6th -- November 6th -- sorry.

THE COURT: You're getting me very confused there with your dates, Mr. Chesler.

MR. CHESLER: Miss King is here to keep me straightend out and she did so. November 6th. I apologize. Paragraph 54, your Honor, of November 6th, '03 complaint, quote, The class period ends on or about October 21st, '03. The very next morning on October 22nd, Reuters ran a story entitled Merck To Cut 4400 Jobs, Earnings Flat, and then they go on to quote from the, article. And here's the only quote from that article that relates to cardiovascular risk which, according to these plaintiffs, was enough to trigger the filing of the lawsuit was, quote, a corrected disclosure to the market under Dura that allowed them to claim loss causation.

Here's the quote. The arthritis drug is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks and the growing perception that its pain-fighting capabilities are no better than traditional painkillers. So, these plaintiffs allege that the statement that Vioxx might slightly raise the risk of heart attacks pushed the stock price down and triggered their lawsuit within days and, by the way, that they claim was what defined the end of the class period, at the close of trading on the day before.

So, all of those warnings that we had misrepresented the safety profile, all of those plaintiffs who alleged unequivocably Vioxx causes heart attacks in publicly filed complaints were not enough to constitute storm warnings. But the statement that the drug might slightly raise the risk of heart attacks was enough to trigger the lawsuit.

Those two propositions cannot be reconciled. No amount of discovery, no amount of my client spending millions of dollars to defend itself is going to change those facts, your Honor. Those facts are etched in stone. Nothing is going to change them and nothing is going to make their complaint an earlier filed complaint.

And lastly, your Honor, just the last point and I'll sit down. The complaint we have moved to dismiss today, the August '04 complaint, says over and over and over again that the very public statements which the plaintiffs contend here were insufficient to trigger the Benak standard, nevertheless, in their words put us on notice that our public statements were wrong.

Paragraph 202, they quote the FTA warning letter and what do they say, quote, It put defendants on notice of the serious risks associated with Vioxx. Paragraph 203, they cite to some of the same articles we cite to on this motion. What do they say, quote, They clearly put defendants on notice of the serious problems discussed herein. Paragraph 207, they point to the same product liability cases on which we rely and what do they say, they say that Vioxx caused -- they allege that Vioxx caused significant personal injuries and even death is also evidence of defendant's knowledge.

Your Honor, we're not the only ones who are reading this stuff. The plaintiffs' bar who brought the product liability cases knew. According to these plaintiffs, we knew. The only people who didn't know are these plaintiffs. The lawsuit is untimely. The record here compared to the Benak record is overwhelmingly stronger and I respectfully submit that they cannot demonstrate they have a timely case. They cannot demonstrate fraud-on-the-market reliance as a matter of law. They cannot demonstrate that there were material misstatements or omissions given all of the information that was in the market. For all of those reasons, in addition to those which we've briefed at length and I have not talked about this morning, we respectfully request that this complaint should be dismissed.

THE COURT: Let me hear from plaintiffs. I'm sorry. There's an individual defendant.

MR. PERSCHETZ: Well, it really is up to your Honor. I speak, first of all, on behalf of Edward Scolnick. I'm Marty Pershetz.

THE COURT: And your argument is everything that Mr. Chesler said and, by the way, you've also got Mr. Scolnick's press release or article.

MR. PERSHETZ: Very perceptive, your Honor. I was going to add that but in the wake of the tsumnami, I don't think it's necessary. There are additional arguments on behalf of Dr. Scolnick, but if your Honor wants to deal with the statute of limitations argument first, that might be appropriate.

THE COURT: Fine. Let me hear from counsel for plaintiffs. Mr. Weiss.

MR. WEISS: This is the traditional dilemma that the PSLRA places the plaintiffs' bar and plaintiffs in securities cases. The defendants come into this court on page 32 of their brief and they state, since the FDA, the medical and scientific community, the financial analysts and the news media were all unable to conclude that Merck's interpretation was wrong, plaintiffs cannot possibly meet this standard when they're talking about our ability to demonstrate scienter.

What the plaintiffs have to have storm warnings of is culpable behavior. And the only people that it is alleged had a duty to speak the truth under 10(b)(5) and who knew the truth was Merck and the other named defendants.

They now want to create an illusion that there was a public debate and everybody as a result of the debate should have become aware that there was a possible lawsuit, everything that Congress didn't want us to lead to when they passed the PSLRA. There should never have been a debate.

We're dealing with a pharmaceutical company that makes pharmaceuticals that have the capacity to kill people. And when people who manufacture pharmaceutical drugs such as that speak and tell the public what they believe the drug does or doesn't do, it has special meaning, even more meaning than the duty under 10(b)(5) that all issuers have. And what did Merck do? Their conduct tells us. Let's look at the facts. Let's look at the words that they used. Let's look at their conduct, their pattern of activity, when measured against what they legitimately should have done. They surely did not have the right to say and do the following, to deny the mechanism-driven CV effects of this drug, repeatedly to predict future growth in the earnings of this drug which was their blockbuster drug, and repeatedly said we continue to grow throughout the class period, to create a phony alternative story that Naproxen had special qualities that prevented the CV effects.

They spent $78 million in direct-to-consumer advertising for three and a half years before including a plausible warning of the CV effects. They threatened doctors. They manipulated test results. They distorted articles in learned medical journals and in virtually every one of their filings with the SEC, their press releases, they spoke that their mantra as a pharmaceutical manufacturing company is that they are safe and they would not put the people who use their drugs at medical risk. In other words, your Honor, they went for the money.

Now, what Mr. Chesler will tell you is, well, you should have been able to discern at that point in time that there was culpable deliberately false information being given by the company, that you should have been able to discern that the head of their medical

department, Dr. Scolnick, himself observed as early as April of 2000 what he already suspected way back in 1997, that there were mechanism-driven CV aspects to this drug. Knowing that, he didn't do the honorable thing. He didn't do what they said Merck stands for. He didn't say to the FDA I'll permit you to put that risk in the warning portion of the label.

Your Honor himself, when he looked at -- when you looked at the label in another context when the plaintiffs made the argument, you said that that label change and what the FDA warning letter said wasn't what the plaintiffs were purporting it to say.

Now, statute of limitations is a fact intensive issue. If you take a look at the panoply of people on Wall Street who are examining this company during this period, you will see something rather remarkable, and I'd like to show you a chart. Keep in mind this is a securities fraud case and what people were being led to believe by the company is that there was this debate and that they didn't have any special knowledge to enlighten people about the debate but don't worry about it, the commercial viability of the company is fine. Maybe because of the debate there will be some reduction in the growth of the sale of this product but not a disappearance of the drug or a marked decline in the profitability of the drug.

This is a chart, your Honor -- I want the defendants to see it also -- of the market action of this stock during the class period, and these green lines show analysts' reports that were issued along the way. We used November -- what is it 6th that the complaint was filed?

MR. COFFEY: That's the date they say we should have filed within two years prior to the complaint.

MR. WEISS: Two years prior to the complaint. There's only one negative downgrade by any of the

market analysts, only one. If you take any point along the way that Mr. Chesler was talking about where so-called information that was storm warnings that should have led us to believe that there was culpable conduct, you'll see that there were positive analysts' reports; indeed, in some instances the highest rating ever given to this stock where you see the star, the yellow star. Only one negative report, and there are cases that say one negative report should not be a storm warning. It's not the tsunami of information that Mr. Chesler is talking about.

This is what Wall Street was looking at and it was believing the company when the company said we believe in the safety of Vioxx.

To make a determination now, your Honor, that at any one of those points there was a sufficient accumulation of information to trigger the duty to make inquiry we think is wrong. This is not a summary judgment stage of the case. This is a motion to dismiss.

Secondly, Mr. Chesler said there was no investigation done. His own brief rebuts that. We have under 10(b)(5) each purchaser of securities, the presumption of reliance based upon there being an efficient market, efficient market means information gets into the marketplace and gets into the price of the stock at any given point in time. We have the right to assume under 10(b)(5) and the efficient market theories that there are people who are out there who are even more sophisticated than a reasonable person, which is the standard that is set forth for statute of limitations purposes, to investigate, to find out whether or not there was culpable conduct.

Your Honor, the defendants themselves admit that nobody, none of these sophisticated people figured out that Merck knew all the time that this was a mechanism-based effect of their drug, not scientists, not the doctors,

not the people who wrote the learned medical journals, not the newspapers, not even the FDA. No one ever questioned to our knowledge the financial capabilities of this drug for Merck.

There's a document that I would like to show the Court that we recently got our hands on. We gave a copy to the defendant this morning but this is a document that was prepared by Merck and it's dated July 2001. It's marked as plaintiff's exhibit 2 and I believe it was used as evidence in the recent trial down in Atlantic City. With the Court's permission, I'd like to hand it up.

THE COURT: Thank you, Mr. Weiss.

MR. WEISS: To show the materiality, your Honor, of a warning of the CV effects, I ask the Court to look at page 17 of this exhibit. It purports to show their forecasts for the drug from 2001 July going forward to 2006. And there's a base and it says under that class CV label precaution, which I believe is what the label required in April of '02. Then it shows upside, 25 percent in '05, if a CV label is milder, no pro-thrombotic language. And then it shows downside, minus 50 percent if the CV label is warning, not a mere precaution.

That was Merck's own estimate of the difference between a warning and a precaution, and they fought like crazy that it not be a warning, even though they knew that a warning should have been the way to go if you wanted to be honest with the public.

That was never explained to the public. They never did anything but give future earnings projections that showed an upswing in the sales of the drug, albeit from time to time not at the same rate of acceleration as they originally predicted.

I mean, this is no different, your Honor, than the judge that handled the Exxon Valdez case observed when he, in the Delaware federal court, said that Exxon

is the weatherman and they're the ones that control what kind of predictions are going to be made.

Here Merck was the weatherman. Merck understood itself internally what the problems were and they never, never, never revealed it. They never revealed it. Even after they said in April '02, which is well within the two-year period, that there may be some lack of clarity in one 10-Q filing concerning the future risk, the risk, the present risk of the use of Vioxx with respect to CV results, after that, in almost every publication that they issued or every press release that they gave, they spoke about the growth of the drug and they spoke about their adherence to the safety of the drugs for their constituent patients.

So, for the defendants now to come into court and say that it's untimely to have brought this action at the end of '03 I think is something that as a matter of public policy should be understood to be very dangerous, because what it is is rewarding the only party that has a duty to speak the truth not to tell the truth when it has the sole ability to do it.

THE COURT: Let me ask you a question, though, Mr. Weiss. All right. Mr. Chesler has indicated that back in May, David Boies, representing a class of plaintiffs who contended that they had been injured by Vioxx, had filed a class action concerning the effect of Vioxx. Now, Mr. Boies is a name which I've heard of before, and --

MR. WEISS: He's a friend of both of us.

THE COURT: -- you and Mr. Chesler have also. Was he somehow uniquely prescient in discerning that there was a problem with Vioxx and initiating that class action which the rest of the bar was not through due diligence going to be able to determine?

MR. WEISS: At that point in time, your Honor, as a matter of law, I don't think he had sufficient information

to make a case like that. As a matter of fact, if you recall, your Honor, when I stood before you the first time when New York State Retirement Fund wanted to replace me as counsel, a year -- I think it was a year and a half after we brought our original case, stood before this Court and said that I didn't have enough information when I filed, when Mr. Brody, who's sitting to my left, filed his case in Louisiana in November of '03. Okay. What --

THE COURT: And maybe under Fifth Circuit law they were right, but I'm dealing with Third Circuit law right now.

MR. WEISS: I understand that, your Honor. But we can't become the prisoner of what somebody decides to file in court we think inappropriately but keep in mind also he was talking about a personal injury case. I don't know the case. I haven't seen the complaint but --

THE COURT: But the case still has at least one core, which is in the face of Merck's vigorous protestations, particularly at that point in time, about the effect of Vioxx and, if I recall correctly, at that point in time Merck is at least still maintaining their argument and may to this day for all I know be maintaining the argument that the results in the VIGOR study were because of the anti-thrombotic effect of Naproxen as opposed to a pro-thrombotic effect of Vioxx. Wasn't that essentially the core of the medical position that Merck was taking at that time, which plaintiffs essentially are asserting misled the public?

MR. WEISS: We allege now that Merck knew the risk, that it knew the effect and that it had the duty to tell, but David Boies or whoever prepared in his office at that time, first of all, to bring a class action for personal injury, I don't understand that at all because I can't remember the last personal injury class action that was ever certified other than maybe a medical monitoring

case many years ago. So, to be bound by what some lawyer decides to do without sufficient evidence, I think sort of recklessly filing a class action with respect to personal injury, should not bind what a securities lawyer should be able to observe to find culpable conduct sufficient to meet the pleadings standards of the PSLRA, which he did not have to do.

THE COURT: All right. Let's fast forward to the FDA warning letter, September what?

MR. CHESLER: 17th, your Honor.

THE COURT: Okay. Now, I don't have the exact language in front of me but --

MR. CHESLER: Exhibit 1 to our papers.

THE COURT: This letter accuses Merck of misrepresenting the safety profile for Vioxx.

MR. WEISS: In only certain respects, your Honor. They claim that it was superior to other drugs and it made claims for the efficacy of it with respect to CV that were at that point unsupportable. In other words, the FDA said you don't have a basis for making these statements. They didn't say that you had a basis not to make these statements. They said you don't have a basis to make these statements and, therefore, it's not something that we think would be appropriate for you to say.

THE COURT: Let me ask you a question, Mr. Weiss, and I will candidly admit that both you and Mr. Chesler have much more experience in the area of securities fraud law than I will ever have no matter how old I get to be, but am I mistaken in my understanding that if a company makes factual assertions about its product which are disseminated to the securities market without a factual basis for it, that that's securities fraud also?

MR. WEISS: Yes, absolutely your Honor.

THE COURT: If we take the FDA's statement here then, which is you are telling the public, Merck, that the VIGOR studies' results are predicated upon in Naproxen's anti-thrombotic activity and not upon a pro-thrombotic effect of Naproxen, and you don't have a basis in fact for making that assertion, you're engaging in misrepresentation. That's what the FDA says here and have I misstated the gist of the FDA warning?

MR. WEISS: Of a certain type, and that type in the chart that I showed you that Merck prepared would have X effect on the price of the stock, if it had said that we know it has thrombotic effects that are mechanism driven by this drug, even Merck admits, even without withdrawing it from the market, the stock -- the sales would have dropped 50 percent from the base.

THE COURT: All right. But what I'm suggesting to you, at least if I read the FDA letter as Mr. Chesler has argued, it's in effect accusing Merck of securities fraud.

MR. WEISS: Of a type, that's correct.

THE COURT: Wouldn't that be a storm warning?

MR. WEISS: Let's even assume for a minute that it is. Let's assume for a minute that it is. As I tried to explain before, your Honor, under the federal securities laws, we as buyers of stock are entitled to rely upon the integrity of the market and under that theory our surrogates that do the investigation become the analysts, the people who are the learned intermediaries. In other words, the law is formed so that it presumes that I don't have to myself do the investigation and read everything. I can rely upon everybody else's assimilated cumulative knowledge.

And now Merck is coming into court and saying that even if I personally as the plaintiff conducted that investigation, which is the second prong to what is necessary for the statute of frauds -- statute of

limitations to bar me from pursuing this case, they would have to demonstrate that a reasonable person would have the culpable conduct that is alleged in this complaint, and they are saying that nobody did, none of them, not the newspapers, not the medical society, none of them, so, your Honor, even if inquiry notice was triggered, I submit they cannot demonstrate that we would have been able to, if we investigated it as a reasonable person --

THE COURT: Let me stop you there for a second.

MR. WEISS: I know there's --

THE COURT: Did you investigate it? Did your client investigate it?

MR. WEISS: There's one case that says that we are charged with any knowledge, if we didn't do it ourselves, that would have been obtainable by a reasonable person's investigation and, therefore, I'm arguing that the surrogate for that investigation are the very people that Merck is now saying never were able to discover --

THE COURT: Mr. Weiss, I have a jury out and unfortunately there has to be a little bit of work done for a transcript which they are looking at and, interestingly, it is a criminal securities fraud trial, so, we're going to take a five-minute break and let my court reporter make sure that the transcript that the jury wants --

MR. WEISS: Well appreciated.

(A recess is taken.)

MR. WEISS: Okay. Your Honor, a couple things. Number one, my colleagues want me to insist on telling you, your Honor, and I think they are a hundred percent right and I thought I said it but I didn't say it adequately, that this is a securities case and what we focus on is what the analysts were predicting for the stock.

If you take a look at this overlay, this is the analysts' comments. These are the analysts' comments after the warning letter came out, and every one of them except for this one that I pointed out before has an upgrade – okay -- or a reaffirmation of a prior prediction for the price to go up, even the red one, the one that spikes down, merely adjusted the future prediction from 88 cents to 78 cents, which was still higher.

So, from the standpoint of a securities investor or a lawyer examining these facts, they see that the warning letter was what Lehman Brothers said in their analyst report, and I read it. We do not believe this letter will be predictive of the FDA's actions on the pending Vioxx label change. There remains our hypothesis that Vioxx will receive a positive label expansion highlighting GI safety in RA. Further, we do not believe that a deleterious label will be forthcoming on safety with respect to thrombotic events.

And they were talking about a warning and it never -- it was never insisted upon by the FDA.

Further, the DDMAC letter was addressed to CEO Gilmartin and signed by the director of DDMAC, Thomas Abrams. Warning letters of this nature are certainly not unusual and in fact almost a staple of the pharmaceutical industry today. However, the fact that Merck is awaiting final approval for a label expansion for the GI safety of Vioxx makes the scrutiny of this letter and its possible implication on that label change very high. Okay.

Now, the label change occurs and what is the market reaction? It goes down and then it comes up again and it keeps on going up. And I have to take a look at the overlay. This is the S & P index so you can see that spike down is consistent with the S & P overlay. And this is the pharmaceutical index which also spikes down at the same

time so you can see that that spike is confounded and it certainly does in evidence that it was as a result of the letter, the entire market spiked down.

After the market absorbs that information, Merck goes up and it goes up at a much faster pace than the rest of the market.

THE COURT: Mr. Weiss, let me ask you this. All right. If I accept your argument about the efficient market theory, wouldn't it logically follow that, in fact, there could never be storm warnings because storm warnings would be absorbed by the efficient market and the price would plummet. In short, the idea of storm warnings is to put a prudent investor on notice to start investigating. Right?

MR. WEISS: Right.

THE COURT: It doesn't mean that the information is supposed to be, for example, the corrective announcement that causes the stock to plunge. Right?

MR. WEISS: Right.

THE COURT: So, in short, for example, if all those analysts' reports had started going negative right after the point in time that the FDA warning letter was issued, I presume that that would have resulted in indeed a plummeting of some sort in Merck stock. Right?

MR. WEISS: I'll accept that.

THE COURT: Okay. What you're suggesting to me is that a fraud can never continue beyond the point in time when storm warnings are sufficient to put one on notice for inquiry notice purposes.

MR. WEISS: I don't buy into that.

THE COURT: Okay.

MR. WEISS: The storm warnings are supposed to be something that is an indicator. It's not proof necessarily. It's an indicator that there's something that should make you investigate that there's a possibility of

culpable wrongdoing with respect to the duties and obligations that one has under the federal securities laws.

THE COURT: Okay. So, let me ask you this. All right. I've got David Boies filing a product liability class action. I've got an FDA warning letter. I've got a New Jersey consumer fraud class action filed within a week or two after the FDA warning letter and, if I recall correctly, the attorney who filed it was a Mr. Squitieri, who perhaps doesn't do securities fraud but, as I recall, the name is not unfamiliar to me for doing, for example, ERISA fraud, ERISA fiduciary cases which tend to parallel securities fraud cases. Would my recollection of Mr. Squitieri's field of endeavor be correct?

MR. WEISS: I don't really know what his practice is.

THE COURT: He files a consumer fraud class action against Merck among other claims.

MR. WEISS: That's the Heindel case, your Honor?

THE COURT: Not Heindel.

MR. CHESLER: Astin.

THE COURT: The Heindel case is way after the statute ran. Mr. Squitieri's case was New Jersey state court class action filed a week or two after the FDA announcement.

MR. WEISS: Your Honor, we now have the Boies complaint.

THE COURT: Right.

MR. WEISS: And the way we read it, and I have to read it quickly, is that he was seeking injunctive relief to accelerate the label change that the FDA wanted to make so that the patients -- the learned intermediaries would get that information sooner.

Now, the FDA letter really didn't say anything more than what was already in the marketplace, and there was

a specific objective that the FDA had at the time, and as Lehman Brothers pointed out, this is common in pharmaceutical applications. If every time the FDA sent out a warning letter it triggered inquiry notice that there's a fraud, an internal fraud, I think that we would be bombarded with lawsuits that the system doesn't want. I think that we have to respect that the PSLRA has heightened pleading standards, that 10(b)(5) has a 9(b) requirement, that lawyers who are looking at these things have to look for culpable conduct, and I suggest to your Honor that there is not an iota of evidence that there was anything in the marketplace that indicated that internally Merck knew that what it was saying was a lie, that its conduct was driven to mislead the public as to whether there was a debate as opposed to actual knowledge, and there's a huge difference.

THE COURT: Well, they had been up to that FDA letter actively promoting the idea that the difference, in vernacular terms, heart attacks between Naproxen and Vioxx was caused by the fact that Naproxen had an anti-thrombotic effect, which in layman's terms would mean tended to prevent heart attacks. Right?

MR. WEISS: Right.

THE COURT: Now, the FDA says in their warning letter you've got no evidence to support that and you're promoting this argument without any evidence. Right?

MR. WEISS: But it didn't say that they had evidence to refute it. That was the difference. The defendants themselves are coming in here and saying this was a debate. I suggest to your Honor that this should never have been a debate, that Merck had the duty to disclose what it knew and instead it deceived the public in a way that no investigation then could have discovered. After these actions were filed, many new facts came about, but at the time the action was filed

there was already another study that came out that showed even in greater detail the thrombotic impact.

And also, and more importantly, from a financial standpoint, the earnings had materially dropped and that's what investors and securities lawyers look at. They look at whether or not the predictions are based upon something that is proper, that it reveals all the known risks going forward, and at the time that that action was filed there was accumulation of factors that led to the filing of a securities case.

Your Honor, I think you have to take judicial notice of the fact that the plaintiffs' bar in the securities arena is not asleep at the switch and especially now with the PSLRA, with big institutions investing large sums of money in companies like Merck, that's one of the most actively traded securities in the country, followed by analysts like crazy, all of whom were giving high ratings for future earnings from this drug because this was the number two -- this was the blockbuster drug for Merck, that they were totally surprised at finding out what Merck's underlying conduct was, which was never disclosed.

THE COURT: All right. Anything further, Mr. Weiss?

MR. COFFEY: If I may, your Honor, on behalf of Mississippi, make one point. As you know, your Honor, we were recently brought on board and after the briefing I do want to point out one thing that I think your Honor ought to consider, which is, as you see on the chart before you, the shaded area begins on November 6, 2001, which is within two years of the Pringle lawsuit being filed and, as you know, the complaint has a host of alleged false statements from May of '99 through October of 2004, and if your Honor were to grant the motion as I see it being made, it seems that it would find

as time barred any action arising out of false statements prior to that shaded area beginning.

However, of course, Pringle was filed within two years of the alleged false statements in 2002 and in 2003, and as your Honor just noted, frauds don't necessarily stop when a case is filed and, indeed, according to the fourth amended complaint, you have false statements being released as recently as August and September of '04, so, your Honor it can't be the case that those statements were untimely filed because they were timely filed, but the Pringle suit was filed within two years of those statements. And I would -- so I believe that that part remains the same and, of course, you may have a debate about whether they were actionable or not, but based on the complaint with the stock drops as light began to shed, I think on this complaint you can't dismiss those on timeliness grounds certainly because they were timely filed. And I won't go back over this chart other than to say that every one of those analysts' reports had a targeted stock price above what Merck was then trading. It would be the rare case indeed, it would be the first case that I'm aware of where you would say isn't that securities fraud when every analyst who's looking at the stock and the news and the FDA warning letter asserts that the stock price is going to go up. That's what this case is about, it's about the stock market, not about whether David Boies could state a claim for medical malpractice. We're talking about commercial viability and these analysts, a reasonable plaintiff investor looking would have to look past all of the analysts' reports and say, you know what, I still think there's a fraud here.

THE COURT: The problem with that argument is that while it's a securities fraud, it's based upon the

conduct of the defendants with regard to their statements concerning medical issues.

MR. COFFEY: And the commercial viability of that drug, your Honor. They were predicting $2 billion in sales in 2002. That's why the stock price was where it was. But your Honor, my larger point is as representing institutions that, as you know, did not appear on the scene here as your Honor has noted until late in the game, at a point in time after the fourth amended complaint was about to be filed, etc., and my client bought 900,000 shares after that shaded area began. Those statements were -- the cause of action as to those statements was timely brought and all of Mr. Chesler's arguments fail as to those statements. That's the point I wanted to make for your Honor. Thank you.

MR. WEISS: There's one other point on that, your Honor. If you take a look at this chart of the time line, you'll see that the differential between the pharmaceutical index and Merck really starts widening after our complaint is filed in November of '03. That's when the real injury occurs. I mean, there's other injuries, there's no question about it, but the spread between the pharmaceutical index and the Merck's performance is at its widest point.

THE COURT: Thank you, Mr. Weiss. Mr. Chesler.

MR. CHESLER: Very briefly, your Honor. The law in this circuit says that if there was a storm warning, the burdens shifts to the plaintiffs to demonstrate that their investigation did not uncover the basis for a claim.

There were multiple storm warnings. Mr. Weiss, I believe, conceded in response to your Honor's question there was no investigation. They seek to make an argument that they instead are able to rely upon what analysts say and not conduct an investigation. That's not the law, first of all. The law requires that they do it, not

that they read the newspapers. We all read the newspapers and, unfortunately, too often plaintiffs file lawsuits just based upon reading the newspapers. That's not what the law in the Third Circuit requires.

There were storm warnings. There was no investigation. The clock begins to run when the storm warnings occurred, when in the words of the Third Circuit in Benak, quote, There is sufficient information of possible wrongdoing to place them on inquiry notice. That is not to be conflated with absolute dispositive proof of a fraud. It is not to be conflated, as your Honor pointed out, with the so-called corrective disclosure that Dura requires the loss causation. If that were the case, you would never have a statute of limitations defense until a corrective disclosure were made. That is not the law.

Last point, your Honor, is counsel quote very selectively from their surrogate investigators, the analysts. They didn't quote from the Bleichroeder report in June of 2000 after the VIGOR study, which said, In our view Merck has not made the case that VIGOR provided the first demonstration of cardio protection with Naproxen in over a quarter of a century in clinical experience. Merck's suggestion that Naproxen would be expected to be more cardio-protective than Ibuprofen and nyclophenac simply doesn't hold much water.

They didn't quote the Bear Stearns report from February 7, 2001, which said, Merck will need to answer questions about significantly higher levels of cardiovascular adverse events for Vioxx versus Naproxen seen in VIGOR.

They didn't mention the Bear Stearns report of February 8, 2001, which said, this is the day of the FDA advisory committee meeting on arthritis, quote, FDA personnel and some of the committee refuted Merck's

hypothesis, noting that Naproxen would need to provide a level of cardio-protection higher than aspirin for this hypothesis to be correct.

They didn't quote the J.P. Morgan report of the very same day, The hornet's nest for Vioxx will be the higher incidence of severe cardiovascular adverse events, including heart attacks, which the FDA views as related to a real Vioxx risk.

And they didn't quote the August 22nd Deutsch Banc Alex Brown report which says the JAMA article, Journal of the American Medical Association, raises a cautionary flag about the risk of cardiovascular events with Cox-2 inhibitors and mandates that a trial specifically addressing the cardiovascular risk and benefit be conducted, particularly in light of their remarkable exposure and popularity.

Your Honor, if those aren't storm warnings, then they ought to take the statute of limitations defense off the books. Everybody knew except these plaintiffs. It's unfortunate for them but that's the law. They waited too long.

MR. WEISS: Just one last point. Everybody knew that Merck was making this into a debate. Nobody knew that Merck didn't believe what it was saying. That is the crux of the case. After those first reports, Merck goes to its all-time high. It reaches $90 a share. The market absorbed all of that. If they had known, if Merck had told the truth about what it was doing, this manipulative conduct and its knowledge already acquired that there was a mechanism-driven relationship, it would have been a totally different story. All of this stock performance would have been way down here.

MR. CHESLER: Your Honor, I'm sorry. One last point, your Honor. Two quick points. The $90-a-share price was back at the end of 2000. By the time of the

FDA warning letter, Merck stock had lost a third of its market value, which the plaintiffs say is of no moment, it's irrelevant to your Honor.

And lastly, as to Mr. Coffey's point, which I neglected to mention before, the law is very clear, your Honor. This is not a continuing event. They don't get to revive a dead case because of a subsequent statement. Once the storm warnings have occurred, once the investigation has not been done and they've sat back while everybody else is saying there's a problem here, while four different sets of plaintiffs' lawyers file these lawsuits, consumer protection, product liability, they don't get to revive it by a later claim and say, well, you're only knocking off the first half of my case, not the other.

THE COURT: Anything further?

MR. PERSCHETZ: If I may briefly, your Honor.

THE COURT: And I haven't forgotten Mr. Scolnick's quote in the newspaper.

MR. PERSCHETZ: I know that and I'm not going to raise it. First of all, with regard to the very last point that was made, I just want to emphasize that Dr. Scolnick retired from Merck at the end of 2002, so, whatever the points that were made about statements would not apply to Dr. Scolnick for that reason as well.

Second off, just one second on the statute of limitations point which is, I want to just go a little bit further about what the law says in this circuit which is In Re NAHC Securities litigation, a 2002 Third Circuit case. The court said specifically that the fact that diligent investigation may not have uncovered the fraud is not enough if in fact the plaintiffs didn't investigate. The law in this circuit requires them to investigate even if they subsequently maintained, even if they're correct, that they would not have ultimately discovered the fraud. I think that's as well an important point.

The only other thing, I don't want to try your Honor's patience, the only other thing I wanted to emphasize specifically on behalf of Dr. Scolnick today is to make clear a point that we make in our brief that really applies only to him and, that is, the division of alleged statements that they allege Dr. Scolnick is liable for under the anti-fraud provisions.

The fact of the matter is that there aren't any statements in this complaint that allege actionable misstatements by Dr. Scolnick and that's for three reasons, and I won't dwell on them. I just want to make sure that the division among those three categories is clear.

One is, and it's the overwhelming majority of statements alleged in the complaint, statements that he did not make and under the so-called bright line rule which has been adopted by the overwhelming majority of district courts within this circuit even though the Third Circuit has not spoken on it, he has to actually make the statements for attribution. Those district courts have adopted the Second Circuit's formulation of that rule after Central Bank, in Shaprio, in Wright vs. Ernt & Young, and this applies to something like, I don't know, 90 percent of the alleged misstatements in the complaint, press releases and the like that Dr. Scolnick had nothing to do with.

The second category of alleged misstatements with regard to Dr. Scolnick has to do with material attributed to him in the 10-Ks of a narrative variety. Those things, in one instance they don't even relate to Vioxx. They relate to Merck generally, and the fact of the matter is that in plaintiffs' brief in opposition to this motion, they specifically acknowledge that they're not claiming that those particular statements made by Dr. Scolnick in the

10-Ks were false. That's in their brief at footnote 25, I believe it is, page 20.

The last category are three individual statements made at disparate times to newspapers and the like, all of which for the reasons set forth in our brief, and I won't dwell on them now, fall into the category of general statements of optimism, puffery, medical opinion, etc., and so forth that have been discussed in various Third Circuit cases, including the Oran case, and those aren't actionable as well.

But before you even get to those, something like 97-98 percent of the alleged misstatements in this case don't have anything to do with Dr. Scolnick and on that ground alone, all of that portion of the complaint should be dismissed against him, as well as the three disparate statements that he made outside the context of the 10-K.

THE COURT: Thank you. Anything further?

MR. BROWER: Your Honor, if I may, with respect to Mr. Scolnick, I invite the Court, I know it's got a lot of exhibits and I don't know the exhibit number but the October 9, 2001 New York Times article in which the quote that your Honor keeps referencing appears, I think it's important for your Honor to take a look at that because what it was was Merck's response to the FDA warning letter in the public.

Whatever response they gave to the FDA that was called for in the FDA's warning letter itself was never made public if it was ever given to the FDA. And what Mr. Scolnick says in that letter is a long description of the history of Cox-2 inhibitors and that some professor years and year ago said maybe there might be some heart problems with it going back before Cox-2 inhibitors.

He said, While the company announced the heart findings to doctors and the public, referring to VIGOR

which was released and was published in the New England Journal of Medicine, it's questionable whether the correct results were published in the New England Journal of Medicine, but results were published. It did show those CV events and it goes on to say, it looked back at the data, it being Merck, from studies using different drugs or dummy pills in comparison to Vioxx and found no evidence that Vioxx increased the risk of heart attacks, Dr. Scolnick said. He said the company decided, quote, The likeliest interpretation of the data is Naproxen lowered, lowered, the thrombotic event rate, unquote, meaning that it protected patients from heart attacks. He added that without the theoretical question raised by Dr. Fitzgerald this is this guy before Cox-2 inhibitors were released no one -- there would have been no remaining question in their mind that there might be an additional interpretation. On the other hand, Dr. Scolnick said, now that the clotting question has been raised, none of the findings to date are enough to prove that the issue is fully reserved. That lack of proof is why the FDA demanded that Merck explain both sides of the hypothesis.

They then proceed year after year after year to continue with the Naproxen hypothesis down to their own brief in this case, your Honor, where there's a footnote still arguing the Naproxen hypothesis. To the extent, your Honor -- and that's clearly Dr. Scolnick explaining to the world, the same person who the minute the VIGOR results were in hand internally said mechanism based as we weren't. He knew the drug caused heart attacks, not that it .was an unlucky event as Mr. Chesler's brief says. There's three possible explanations. This unlucky group of people and it's just a coincidence that more people that took Vioxx had thrombotic events or Naproxen is cardio-protective

which they still argue in their brief, or the third possibility that Vioxx is pro-cardio.

The fact is Dr. Scolnick knew it was pro-cardio. He proceeded to spin the story that they don't know what it is. They picked the best explanation they can find. The idea of the Naproxen hypothesis was not something brand new or something that suddenly came to light with the FDA warning letter. It's something that Merck was explaining to analysts and doctors for months and months and months since the study came out because they needed to explain those additional heart attacks versus the Naproxen group. Therefore, there was no new information in the FDA warning letter. What the FDA warning letter uses is some very strong language because it's coming from the division of drug marketing, it's not coming from the medical side, and the letter itself over and over and over again says there's no knowledge of why the Vioxx group had more heart attacks. It just had more heart attacks. And they have no reason to believe that Merck knows the reason. They certainly don't know that Merck believed it was mechanism based.

This case goes to the economic viability of this drug and if you look at every drug, I believe your Honor's Heindel decision does talk about this, lots of drugs have some side effects. Some people might be susceptible to some of those side effects, but the fact of the matter, the fact that the drug might have some side effects or might not be cardio protective like Naproxen would not be a reason for investors to worry about their investment in Merck.

The question here is in September of 2001 or in fact any time before November of 2001, if I'm an investor in Merck, am I worried whether or not Vioxx is going to make me money or lose me money, and there's no question based on this chart if you follow along and you

see how it patterns against the pharmaceutical industries and the S & P and, of course, you've got to factor in there September 11th is in the middle there right about that time besides, so, that's having an effect during that period, so, you get past that window of September 11 and the impact of September 11, and what you have is the stock going up and up and up. What you have is every public document, every 10-Q, every earnings release, Merck referring to this drug as one of its five drivers of revenues and growth.

If I'm an investor, and that's who we represent, I look at this information, I look at the analysts' reports which their job is to digest this information, they are constantly looking for what's going on. They're trying to look at the future because analysts only care about the future, they don't really care about the past, and you look at what they did and what they were saying going forward, and what they saw was a drug with the worst of the results over there. The one analyst who downgraded and downgraded from a high buy, by the way, didn't downgrade like don't buy it, but the one guy who downgraded, that said three billion in sales, he's projecting three billion in sales at the time when the drug was selling less than two billion a year, well, clearly he had no concerns over the economic viability of this drug and the fact that this drug was going to drop $3 billion a year essentially net on to the bottom line of this company through the life of its patent.

It's not until October when, in addition to what Mr. Chesler says, 400 people were being fired -- I'm sorry -- October, 400 people were being fired, there were other readjustments if you look at the press release, recent, recent studies showing -- and they're referring to the Harvard study that came out that confirmed greater number of heart attacks from Vioxx and Celebrex. Then

you have what the Court of Appeals case has discussed as these culmination of events that tell investors that this drug may be in trouble and it's not going to drop two and a half or $3 billion a year to the bottom line of this company, and if you look at the chart, your Honor, that's in front of you, you notice the first time that line persistently falls off both the S & P and the pharmaceutical index is in October 2003. It falls, it lays flat and it lays flat, your Honor, until when, until September 24, 2004, when the drug it's learned has no commercial viability. It's not going to be reduced commercial viability, which is what people believe in October of 2003, it's going to be no commercial viability. And you can see that line drop right off and that's the result of people learning the truth about the drug, that it's so bad it can't be sold.

THE COURT: Thank you. Anything further?

MR. PERSCHETZ: The only thing I want to say is they have not charged that Dr. Scolnick made a false statement in the New York Times article and notwithstanding the effort to rekindle the statute of limitations argument in what we just heard, what we heard was that according to the plaintiff's theory, there can only be storm warnings when the alleged truth is revealed. That clearly is not the law. That goes well beyond storm warnings. Thank you, your Honor.

THE COURT: Mr. Chesler, anything further?

MR. CHESLER: No, your Honor.

THE COURT: Thank you very much, everybody.

MR. BROWER: Your Honor, one housekeeping matter. We wanted to make sure, I tried sneaking these up. I usually ask to approach. One was the chart showing the analysts with the overlays. I want to make sure you have them.

THE COURT: Please give them to my law clerk in the jury box and we'll make sure we have them.

(Whereupon the proceedings are adjourned.)

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 07-2431 & 07-2432

IN RE: MERCK & CO., INC. SECURITIES, DERIVATIVE & "ERISA" LITIGATION

ORAL ARGUMENT

June 24, 2008

JUDGE SLOVITER: Mr. Coffey?

JOHN COFFEY: Good morning -- the last few minutes. May it please the court, I'm John Coffey of the firm Bernstein, Litowitz, Berger & Grossmann. Counsel to the Mississippi Public Employees Retirement System, which is one of the co-lead plaintiffs in this case, as well as the respective class. With your permission I'd like to reserve five minutes for rebuttal.

By way of preview I propose to give a little bit of context, discuss the law for a little bit.

JUDGE SLOVITER: Okay, you know that -- you've been sitting here. You know we read the briefs.

JOHN COFFEY: Very well.

JUDGE SLOVITER: We read the appendices, so we can interrupt you at any time. [OVERLAPPING] So you start and then we'll ask you questions.

JUDGE TRUMP BARRY: And also we're interested in the most important points and not --

JOHN COFFEY: Very good. Well, Your Honor, because what we're talking about here is what you take away from a mix of information, it's obviously very important to go through what is actually in the record and what can be taken from that. But before we do that I think there's a very important piece -- point to be made about the law. We're talking about the VIGOR study and starting there. And it was a study that was conducted so that Merck could hopefully prove that there were positive GI benefits as opposed to traditional pain relievers. And the results of the study showed that that was in fact the case. Statistically significant better GI results.

JUDGE: The VIGOR study?

JOHN COFFEY: Say again?

JUDGE: The VIGOR study.

JOHN COFFEY: The VIGOR study, I'm very sorry, thank you -- the VIGOR study. It also showed data that wasn't so good, which was that there was a statistically significant difference in the rate of cardiovascular events between those on Vioxx and those on Naproxen. Now, the data -- that data was known, but what wasn't known was the reason why. And two possible explanations...

JUDGE SLOVITER: Well, is that really the issue? Or is the issue the effect of whatever health problems resulted on the market -- on the commercial prospects? Isn't that really what's at issue?

JOHN COFFEY: It is. As we say in point one of our brief, that's the gravamen of the complaint. And because this is a securities case, not a products liability case, that is important. But what I am prepared to demonstrate today is that even if you accept the defendants' proposition that this is about the safety profile of Merck, there's still a question of fact here. When you add --

JUDGE SLOVITER: Well, the question is when there were storm warnings, when...

JOHN COFFEY: Well, it is when there were storm warnings. And, of course, the court is guided in this de novo review by the teachings of Mathews...

JUDGE SLOVITER: Well, when do you think there were storm warnings?

JOHN COFFEY: No earlier -- well, certainly the question today is was there any before November 6, 2001? And there's clearly a question of fact about that.

JUDGE SLOVITER: Well, why wasn't the New York Times article on October 9th, 2001 reporting that there was a troubling question about whether Vioxx could or was causing a slight increase in the risk of heart attack -- why wasn't that enough to give a storm warning that it would affect the commercial...?

JOHN COFFEY: The New York Times article?

JUDGE SLOVITER: Yes, October 9th, 2001, which is before November.

JOHN COFFEY: Because nothing in that article was different. The District Court found that it was a remarkable change...

JUDGE ROTH: Well, it was different because in that article a representative of Merck said that either Naproxen lowers the heart attack rate or Vioxx raises it.

JOHN COFFEY: Your Honor, that's not news. That's not news...

JUDGE ROTH: Okay, and Merck is admitting it.

JOHN COFFEY: No, they're not, Your Honor. Because in the briefs and in the District Court opinion you need to look at what's missing. And if you turn to -- I believe it's page 10 of the brief, they have the headline, which is Dr. Scolnick saying, "It's binary. It's either-or." Okay? And then they have a block quote in the brief where he talks about the need for more study. Look on

page 2367 of the brief to see what's missing. And I'd like to read what's missing.

JUDGE SLOVITER: 2367 of the appendix. You don't mean of the brief.

JOHN COFFEY: It's 2367. And, again, Dr. Scolnick says there are two possible interpretations. That is not new news. Merck said that in its March 27, 2000 press release. It said it throughout. It said in the Arthritis Advisory Committee meeting in February of 2001. It was always saying, "Hey, there are two solutions -- two explanations." What it says, what Dr. Scolnick then says in the part that is not in the brief and not in the District Court opinion is that they still maintain it's the Naproxen hypothesis. He says...

JUDGE SLOVITER: [OVERLAPPING] Yeah, but the question is what gave the warning that it could affect, might affect, would affect the commercial...?

JOHN COFFEY: Nothing, Your Honor. And I think that's an important...

JUDGE TRUMP-BARRY: [OVERLAPPING] Baseball season -- here's one right over the plate. What about -- was there any effect on the stock price after the New York Times article?

JOHN COFFEY: There was not only no effect, no effect on the stock price. This stock covered by a dozen analysts, there wasn't a single analyst report issued on the heels of this supposedly blockbuster revelation. And the next report that did come out by Morgan Stanley in, uh, late October of 2001, didn't say you can't trust Merck, didn't say it's going to destroy the commercial prospects. But what they said -- and this is in the record of A3082, um, they set their target price for Merck at $80. It was then $69. That is not a company in trouble. That does not say that the prospects are bad. In fact, that notes the following: It notes that European Union

regulators had just permitted a label change to expand the use of...

JUDGE SLOVITER: [OVERLAPPING] Well, what happened in November 2001 that you think started a two-year statute? You say that -- in response to my question, I think you said November 2001 -- what happened in November 2001 that was new according to what you say wasn't new in the New York Times?

JOHN COFFEY: Well, Your Honor, nothing happened November 1. That date is...

JUDGE SLOVITER: [OVERLAPPING] So why does the statute of limitations run then?

JOHN COFFEY: I don't believe it begins to run then. We're talking about an opinion.

JUDGE TRUMP-BARRY: You say your first storm warning was the Harvard study, right?

JOHN COFFEY: Exactly.

JUDGE TRUMP-BARRY: In 2003?

JOHN COFFEY: It was the first time -- what's important -- why this case is different than Mathews or Benak or NAHC -- there are lots of reasons why. But this is a case that involves opinions. And so when you're talking about culpable misconduct it's an opinion. And you look to Virginia Bankshares, you look to this Circuit's decision in Shapiro. Judge Sloviter, we have your decision in Eisenberg v. Gagnon which says that you're entitled to take someone at their word unless you have a reason to believe it's not held in good faith or there's independent data that says it's not true. There is nothing in any of these supposed storm warnings that suggest that Merck did not believe what it said. And if you read...

JUDGE ROTH: [OVERLAPPING] What about the FDA warning letter?

JOHN COFFEY: Four points, Your Honor. First, nothing new. This is....

JUDGE SLOVITER: September 21st, 2001.

JOHN COFFEY: Correct. First. It's nothing new. This is a securities case.

JUDGE ROTH: The FDA is telling Merck "Stop misrepresenting Vioxx. You're only showing one side of the story."

JOHN COFFEY: To 100 doctors and 2,000 pharmacists. Those were the people who were getting it. It said nothing about them hiding the scientific data, which had been public since March of 2000. If we alleged a security claim saying that they failed to tell these doctors at these conferences about the other side of the either-or story, we'd be laughed out of court. Because in a securities context this Circuit says investors were on notice as of March of 2000, when Vioxx said it could be either-or. And throughout the record it was either-or.

JUDGE TRUMP-BARRY: Baseball season. A week after the warning letter, the stock was higher than it was before.

JOHN COFFEY: Well, Your Honor, yes. There's a lot of talk about whether in the District Court's opinion -- and if you look at the analyst reports...

JUDGE TRUMP-BARRY: The District Court didn't deal with the stock issue, though.

JOHN COFFEY: It did not.

JUDGE TRUMP-BARRY: And that's kind of interesting. Because it's not -- it is a factor, I suggest it might be a very important factor -- it's not the only factor. But the District Court did not deal with the effect of the warning letter or effect of the New York Times on this stock price.

JOHN COFFEY: It did not. And, yes, the defendants say there was a slight drop in the stock. But in 16 of the

following 25 days, after the FDA letter, the stock was higher. You have six analysts are in the record. Every one of them maintained their rating, four of them were buy; three or four of them -- excuse me, four of them set a target price a year from now of $80. The stock was at 64. So a reasonable investor looking at the reaction, not by, um -- looking at the reaction by trained professionals, saying, "Not to worry. The stock is going to increase by 25 percent in the next year" -- not discussed in the District Court opinion.

What it did say -- the worst they could say in light of the FDA warning letter was, you know, "They may not have their growth rate, their rate of penetration of the pain reliever market be quite as good." So it wasn't rain or thunder or lightning, it was weathermen on the scene at the time saying, "You know, tomorrow's going to be sunny and clear but it may only be 79 degrees instead of 80 degrees." And the judge below did not discuss that. And that's, that – you talk about what a reasonable person of ordinary intelligence would take from that...

JUDGE ROTH: Would a reasonable person of ordinary intelligence base their security transactions on what stock analysts are saying, disregarding completely what's going on with the company?

JOHN COFFEY: Well...

JUDGE ROTH: Aren't they put on notice by what the company is saying? Aren't they put on notice by the probable future of the company's growth or problems by the comments on what the company is actually doing with its product, rather than the comments of the stock analysts, who may really understand or not understand what's going on?

JOHN COFFEY: Well, Judge Roth, if this were limited to what the company were saying, this would be

an even easier question. Because they were reassuring -- they said they had 28...

JUDGE ROTH: [OVERLAPPING] That's not my question.

JOHN COFFEY: The answer is yes, they can rely on analysts. And I think the law is pretty clear. The Supreme Court in Virginia Bankshares referred to the sensitive antennae of analysts. This court -- and I'm happy to get the cites for when I come back up in a few minutes -- talk about -- Oran v. Stafford is a good example. The fact that the market didn't move and that the analysts didn't comment was indicative that the material at issue was immaterial. And so, yes, it's part of the mix.

JUDGE ROTH: But what if we look at the material at issue and decide that it is very material? In spite of the analysts' failure to pick it up, that this is very material information.

JOHN COFFEY: Well, I think it would be imposing your [OVERLAPPING] -- I think you would be imposing -- I think that would be in violation of Rule 12(b)(6). I mean, you have to come up with evidence that they didn't believe what they were saying. The record is completely absent as to that. In fact, the FDA in the warning letter says, "The Naproxen hypothesis might be a possible explanation." It reinforced that the either-or was a valid debate. It didn't say, as in many other cases, "Merck, you're wrong." There were lots of -- there was a lot of information out there...

JUDGE ROTH: Look, if there's no more than either-or, isn't that something I ought to be worried about if I'm going to invest in that company? That they've got a product that either-or -- uh, and if it's one side of that hypothesis, that's bad, bad news.

JOHN COFFEY: Well, no, Your Honor. Because, again, the standard for inquiry notice is culpable conduct. And until you have evidence that they don't believe their interpretation of the data, it's not culpable. But the -- the most important thing, or one of the most important things an investor can know is that despite the District Court's view that Merck ceased to be reliable after the warning letter was the FDA, which presumably read the FDA letter, expanded the label at April 2002. It allowed more people to get Vioxx. That is a very reassuring sign. The very people who did it in the context of advertising -- you're not telling every doctor every fact that we, the Third Circuit, presume the market has known since March of 2000. Shame on you. Write 100 letters. 2,100 letters. But the FDA and the European Union after those supposed storm warnings expanded the use. They just -- they didn't put a warning in the label, they put a precaution that disclosed in a label the results of the VIGOR test. And that's what these lawsuits were about, was about disclosing in the label...

JUDGE SLOVITER: I know that your red light is on, but I do want to ask you a question before you sit down. The District Court granted the motion to dismiss. This isn't after summary judgment. Right? It was motion to dismiss. Um, what would you be able to show, do you think, on a summary judgment record, um, to show -- to prove to the District Court that it should be a different statute?

JOHN COFFEY: Well, Your Honor, obviously we would have discovery and -- or...

JUDGE SLOVITER: A discovery of whom and for what?

JOHN COFFEY: Well, on the reassurance prong at least we would be able to investigate what has come to

light as recently as the JAMA article two months ago, about how Merck was secretly writing -- ghostwriting these articles...

JUDGE SLOVITER: [OVERLAPPING] No, no, all that does is show knowledge by Merck, but what about -- what about the statute of limitations and what the investors would've known?

JOHN COFFEY: Well, what we could show is that...

JUDGE SLOVITER: [OVERLAPPING] You know, what would you show with respect to storm warnings?

JOHN COFFEY: The earliest storm warning would be in October of 2003, when an objective study sponsored, uh, by Harvard and Merck in part at the Brigham and Women's Hospital. This is the Harvard study.

JUDGE SLOVITER: Yeah.

JOHN COFFEY: And it said, there -- in a controlled test, Vioxx v. Celebrex, that Vioxx had 37 or 39 percent more higher instances of cardiac. And that -- what happened then, the stock dropped. And, and Vioxx started to tear back. That was the reaction.

JUDGE SLOVITER: Okay, let's hear from your friend on the other side. You've reserved quite a bit of time for rebuttal.

EVAN CHESLER: Good afternoon, Your Honors, my name is Evan Chesler. I represent Appellees. I want to start exactly where the focus of the court's comments to counsel have been. Uh, first of all, respectfully, we need to focus on what the storm warnings standard...

JUDGE SLOVITER: [OVERLAPPING] You have to stand a little bit apart.

EVAN CHESLER: Sorry. Is that better?

JUDGE SLOVITER: [OVERLAPPING] That's fine. Yeah.

EVAN CHESLER: We need to focus on what the standard is, and I want to talk about the stock price movement specifically, Your Honors, come to what the facts are in the record about the stock price. The standard, as this court has articulated over and over again -- NAHC, for example, and the Benak cases, were there facts sufficient to show a reasonably prudent investor that there was the possibility, the possibility of a fraud? Not has there been a loss causation movement in the price of the stock that demonstrates the fact of a fraud.

JUDGE TRUMP-BARRY: Parenthetically, the standard is possibility. Matthews uses both -- possibility and...

SEVERAL: [OVERLAPPING] Or probability.

EVAN CHESLER: Yes, Your Honor, it does, and that precedes both the NAHC and the Benak opinions, where this court said possibility. And, in fact, plaintiff's counsel, co-counsel Mr. Weiss in the District Court argument was asked specifically by the District Court what the standard was and he used the proper phrase, possibility. So whether or not there was a stock movement, respectively, is not relevant to the question of whether there was the possibility of a fraud here.

JUDGE: Haven't our cases also spoken of the probability?

EVAN CHESLER: The last case of which I'm aware in the Circuit, Your Honor, that used probability is Mathews. Mathews precedes the other cases...

JUDGE SLOVITER: [OVERLAPPING] In other words, we really -- what you're saying, I think, is that we really have to try to resolve the inconsistency...

JUDGE TRUMP-BARRY: [OVERLAPPING] What Mathews did in two -- at two different points, it was quoting what the District Court had said. And in one the

District Court had said possibility; and one the District Court had said possibility...

JUDGE SLOVITER: [OVERLAPPING] Probability.

JUDGE TRUMP-BARRY: [OVERLAPPING] And I don't think Mathews ever decided -- the issue wasn't...

EVAN CHESLER: I agree. And in NAHC this court said quite specifically -- this is now 2002, storm warnings, quote, "sufficient information of possible wrongdoing to place them on inquiry notice or to excite storm warnings of culpable activity."

JUDGE SLOVITER: I'm sorry, I took you off your -- you were saying something and I, I stuck my question in and questioned you about possibility versus probability. Would you go back to before I interrupted you?

EVAN CHESLER: Yes, Your Honor. What I was saying was this. Whether or not there was a stock price movement is irrelevant to the storm warnings questions. And, indeed, there was colloquy between the District Court and counsel for the plaintiff on this exact point, 'cause they made the point in argument below and the court asked counsel below "Are you saying that you have to see the downward movement of the stock price to show that there was, in fact, a loss that occurred as a result of the so-called disclosure of the truth here?" If that were the case, then you'd never have the statute of limitations triggered until you had the entire elements of the action before you, and counsel conceded below that they were not taking that position.

So the question of whether...

JUDGE SLOVITER: [OVERLAPPING] Well, what do you think we -- is the position we should take?

EVAN CHESLER: I think, Your Honor, the position this Court should take is the position it's taken now in the NAC -- NAHC case and the Benak case, which is

when were there sufficient facts to show the possibility -- let me focus on those facts.

JUDGE SLOVITER: But what I think I was asking is what about the effect on the market? I think you got up to say it's irrelevant, uh, and, um, how do you put that together with your possibility-probability?

EVAN CHESLER: Yes, Your Honor. The ultimate effect on the market is not irrelevant, because that, of course, relates to whether there is ultimately a cause of action or not. The question here is when is there a trigger that starts the duty to inquire? Now, there may or may not be an adverse effect upon the market when that duty first pertains, because there may be something that suggests a storm warning and it turns out there was no cause of action. That's the reason that the Congress has given potential plaintiffs two years to investigate. Suppose they investigate -- which these plaintiffs never did -- and they find that there was no cause of action, there was no harm to the market? The whole point of the statute of limitations is to start a period of inquiry within which the plaintiff must conduct an investigation or else be deemed to be on inquiry notice as of the date of the storm warning, and either file its lawsuit or not file its lawsuit.

JUDGE SLOVITER: What's your date that you would think the storm warning came in?

EVAN CHESLER: I don't think there's any question, Your Honor, that the date was later than the FDA warning later -- letter. Judge Chesler said, "I don't need to reach that question."

JUDGE SLOVITER: Well, what are you telling us?

EVAN CHESLER: I'm telling you the date of the FDA warning letter. And I'll explain exactly...

JUDGE SLOVITER: [OVERLAPPING] That was September 21st, 2001?

EVAN CHESLER: That was September 21st, 2001.

JUDGE TRUMP-BARRY: [OVERLAPPING] What previously nonpublic information did the FDA's warning letter disclose to the investing public? It certainly didn't warn investors that Merck was concealing safety information.

EVAN CHESLER: It said the FDA, the cop on the beat said, "You, Merck, have misrepresented the safety profile of this drug. You have no factual basis for the Naproxen hypothesis. You have never disclosed that you have no factual basis for it." And it used explicitly the word misrepresented. This, Your Honors, is a fraud case.

JUDGE TRUMP-BARRY: But the public, the investing public already knew about this. The possible risk.

EVAN CHESLER: [OVERLAPPING] No, Your Honor -- there's no question the investing public already knew that as a result of the VIGOR study, five times as many people had experienced cardiovascular problems as on the Naproxen arm. But what the FDA said for the first time -- and it's why the District Court said he could find that the storm warnings had started there but need not reach it -- it said, "You, Merck, have misrepresented the basis for that hypothesis."

JUDGE SLOVITER: [OVERLAPPING] Is the FDA warning letter to Merck public?

EVAN CHESLER: Absolutely. There were no less than 11 major press articles, including the Wall Street Journal, the New York Times, USA Today within five or eight days after the FDA warning letter was issued. 11 public articles. There were three lawsuits filed within a week.

JUDGE TRUMP-BARRY: And what happened to the stock market afterwards?

EVAN CHESLER: The stock market lost 6.6 percent of its market capitalization within the five days after the warning letter. And that's at record 1773.

JUDGE TRUMP-BARRY: And on October 1st, the stock closed at a price higher than it had before the warning letter was published.

EVAN CHESLER: Absolutely, as is often the case in securities fraud cases. And the question under the Reform Act, which I'm sure your Honors are well aware, is what happens to the average trading price for months thereafter under the Reform Act in order to determine whether there's been sufficient injury?

JUDGE 2: But then the months thereafter - how can you pin that to the warning letter?

EVAN CHESLER: I'm not suggesting you can. My point is the fact that the stock price went up five or six or eight days later is not at all evidence that there was no impact of the warning letter.

JUDGE TRUMP-BARRY: I'm not so sure it isn't. I mean, the weight to be afforded that is another matter. But it certainly, one can argue, is -- is evidence of the fact that the investing public wasn't partic -- it wasn't new to them.

EVAN CHESLER: Well, Your Honor, I would respectfully disagree. And I would like to point, Your Honor, to what the evidence shows of what happened to the market price when the plaintiffs claimed they had a basis for filing the lawsuit in the fall of 2003. The stock price changed after the supposed revelation about the Harvard study almost exactly the same percentage as it changed in the five days after the FDA letter.

JUDGE TRUMP-BARRY: Oh, but then it went way down. The Harvard study -- the Harvard study was bad for Merck.

EVAN CHESLER: Well, Your Honor, let's focus on the Harvard study...

JUDGE TRUMP-BARRY: [OVERLAPPING] That's when they pulled -- they pulled the drug.

EVAN CHESLER: No, Your Honor. No, they pulled the drug a year...

JUDGE TRUMP-BARRY: [OVERLAPPING] A year, that's right. But it was collapsing after that.

EVAN CHESLER: Long after the plaintiffs had filed their lawsuit and claimed that they had an adequate basis. And, Your Honor, I want to go to the question of these assurances. If you look at Paragraph 291 of the complaint in this case, these are what the plaintiffs have themselves alleged. In Paragraph 291, they're talking about the disclosure of the Harvard study, this terribly important study, they say, which is the seminal difference between the fall of '03 and the fall of '01. If I may just point out to your Honors what they say?

Paragraph 291. On November 2, 2003, four days before they filed this law -- the first lawsuit, in the face of the October 30th Wall Street Journal article, which disclosed the Harvard study, Defendant Reicin, Executive Director of Clinical Research for Merck, publicly denounced the study and announced, quote, "In our placebo-controlled randomized trials we have found no significant difference between Vioxx and placebo." Defendant Reicin also stated, "Randomized clinical trials are the gold standard and this isn't such a trial." Your Honors...

JUDGE SLOVITER: Mr. Chesler, why shouldn't we let this go to summary -- to discovery? Why should this be -- there's really an issue as to which state is the storm warning state? I'm not sure, frankly, what discovery would show on that.

EVAN CHESLER: Your Honor, I'd like to...

JUDGE SLOVITER: [OVERLAPPING] I'm concerned that the District Court did this as a motion to dismiss without hearing what maybe experts in the field would say was the relevance of what happened in the market...

EVAN CHESLER: May I respond?

JUDGE SLOVITER: Yeah, sure, respond. It's a question. [CHUCKLES]

EVAN CHESLER: Yes, it's a fair question. And you asked counsel that question and counsel talked about what Merck was thinking, which is irrelevant to Your Honor's question. No amount of discovery, no amount of inquiry is going to change the public record. And as this Court has held...

JUDGE SLOVITER: [OVERLAPPING] Yeah, but the question is what is the relevance of the public record to the legal issue of the storm warnings? We really don't know what experts in the stock market, um, would -- would say, do we?

EVAN CHESLER: Let me respond to that.

JUDGE SLOVITER: Yeah. I mean, I don't feel I am. I don't look at it.

EVAN CHESLER: The public record, Your Honor, is the entirety of what is relevant to the storm warning standard. This court has held it is an objective standard, it is irrelevant whether any particular plaintiff read any particular note or article that's a storm warning. The public record is etched in granite. Discovery will never change it. The fact that all of those lawsuits were filed accusing Merck of exactly the same misrepresentation more than two years before plaintiffs filed; the fact that the FDA accused them of misrepresentation -- discovery will not change that and there is no role for expert testimony on the marketing...

JUDGE TRUMP-BARRY: [OVERLAPPING] What did those lawsuits disclose to the, uh, investing public? Most of them were just boiler plates and allegations.

EVAN CHESLER: The lawsuits -- the lawsuits disclosed, the lawsuits disclosed that, in fact, very much what the FDA said in its warning letter. That there was no basis for this Naproxen hypothesis that, in fact, the company allegedly has misrepresented the safety profile of the drug. And people who supposedly sustained heart attacks or cardiovascular events...

JUDGE TRUMP-BARRY: But isn't that just what the FDA warning letter said? I don't know what's new in, in the lawsuits for purposes of establishing a storm warning.

EVAN CHESLER: Fundamentally one thing -- critically. The plaintiffs took the position below and here that in order for the clock even to begin running under a possibility standard -- and we disagree with their interpretation, but they took the position that they even had to know that there was a basis for scienter for knowing misrepresentation. That's their position. The FDA said, "You have knowingly misrepresented the facts." This is analogous to a situation where we're looking at accounting fraud allegations and the SEC puts out a warning letter saying, "We believe, the SEC believes you've knowingly misrepresented your financials." And then the plaintiffs come in and say, "Gee, we had no basis to think there was a possibility of a fraud. Why should we think there was a fraud, because the people charged with policing the financials said they thought the company had misrepresented the financials." [OVERLAPPING] Here, the people charged with the responsibility of the safety of drugs said, "We believe you've misrepresented the safety profile of the drug."

Your Honors, read Paragraph 6 of this complaint. The first paragraph that engages in any substantive discussion of this case. What does it say? It says, "We have misrepresented the cardiovascular risk of the drug." And in Paragraph 9 they say, "Because we've misrepresented the cardiovascular risk of the drug, we have misled the market about the financial viability of the drug." That's their complaint.

JUDGE SLOVITER: The letter sent to Merck stated that the exact reason for the increase MIs observed in the Vioxx treatment is unknown.

EVAN CHESLER: Exactly.

JUDGE SLOVITER: So it didn't necessarily say that it came because of Vioxx as distinguished from Naproxen.

EVAN CHESLER: Your Honor -- I would urge your Honor to look at the language...

JUDGE SLOVITER: [OVERLAPPING] And it cautioned that its promotional campaign was not fully accurate. It wasn't as damning as you have represented.

EVAN CHESLER: Your Honor, if you look at -- if you go through the text of the letter, which begins at 713 of the record, A713, you will see that on three or four separate occasions the FDA says, "Merck has misstated its basis, it has misrepresented the safety profile of the record." Remember, Your Honors, the issue here is not whether all of the elements of the offense are laid out in the public record. The question is, is there the possibility that a fraud's been created?

Your Honor held recently in the Colachico case that the FDA is the agency that has the expertise to look at safety of drugs.

JUDGE SLOVITER: Yeah, but what the FDA here did is entirely different than what they did in...

EVAN CHESLER: In a different context, I agree.

JUDGE SLOVITER: Sure.

EVAN CHESLER: But the agency that has that responsibility told the public markets and was reported on in 11 articles in five days "You have misrepresented the -- the safety profile of this drug." The only question, the only question...

JUDGE TRUMP-BARRY: [OVERLAPPING] But the investing public was already well-aware that Merck's Naproxen hypothesis was not proven.

EVAN CHESLER: But respectfully, Your Honor...

JUDGE TRUMP-BARRY: [OVERLAPPING] And that as a result, Vioxx could have pro-thrombotic qualities. I mean, this is not new.

EVAN CHESLER: What was new, what was new was that the FDA said -- the people charged with this responsibility said, "You, Merck, have misrepresented that there is a basis." The fact that they accuse them of fraud and made them notify all of the health carriers was critical...

JUDGE SLOVITER: [OVERLAPPING] They didn't accuse them of fraud.

EVAN CHESLER: Your Honor, that's exactly...

JUDGE SLOVITER: [OVERLAPPING] I mean, that's a little strong.

EVAN CHESLER: Well, the District Court, the District Court I think correctly used the phrase "direct and unequivocal accusation of fraud."

JUDGE SLOVITER: Well, it's the District Court's opinion that's on appeal.

EVAN CHESLER: But, Your Honor, misrepresentation is the sine qua non of fraud and that's what they accused them of. May I make one last point -- I see my time is up.

JUDGE SLOVITER: Sure.

EVAN CHESLER: The October article, which Your Honor asked counsel about, which was also more than two years before.

JUDGE SLOVITER: In the New York Times, yeah.

EVAN CHESLER: Involves -- not only has the FDA now said, "We're accusing you of misrepresenting the safety profile," but now Dr. Scolnick says, "It may be that there's an increased risk of heart attack." He doesn't say he knows 'cause he didn't know. But now the company itself is saying, "There may be an increased risk of heart attack." And what the judge said correctly was "If the standard is do I now have enough to think there's a possibility, I should start inquiring and I may find no basis -- in which case no harm, no foul..."

JUDGE TRUMP-BARRY: We -- the test for storm warnings is whether a reasonable investor of ordinary intelligence would've discovered the information and recognized it as a storm warning. Correct?

EVAN CHESLER: Yeah. Would've thought there was a basis -- a possibility of a fraud to begin inquiring...

JUDGE TRUMP-BARRY: Isn't reasonableness a question of fact?

EVAN CHESLER: Your Honor, reasonable prudent -- yes, it's an objective question that can be resolved if the facts are not going to change, and they're not -- the public record facts are not going to change. And the court had an appendix this thick, which we took judicial notice of, because it was all publicly available information. Those facts will never change. And the court concluded that on those facts a jury could never conclude that the clock had not started running as of the time of the October of 2001 New York Times article.

JUDGE SLOVITER: Thank you.

EVAN CHESLER: Thank you.

JOHN COFFEY: Your Honor, I do commend the court to read the full text on Page A654 in the New York Times article, where after presenting the either-or, the binary, the two possibilities as they had for a year and a half, Scolnick says that they had done additional studies and, quote -- this is from the article now -- quote, "It found no evidence that Vioxx increased the risk of heart attacks, Dr. Scolnick said." Unquote. And then it goes on to talk about the Naproxen hypothesis. He, he says, in fact, no one would have a question but for a question raised by...

JUDGE SLOVITER: [OVERLAPPING] Is there any place in this inquiry with respect to storm warnings or expert testimony? Is there any -- I'm trying to figure out...

JOHN COFFEY: [OVERLAPPING] I think a trial -- perhaps -- you asked the question about summary judgment.

JUDGE SLOVITER: Yes.

JOHN COFFEY: And I'll have to think what your precise opinion was -- I can't... I'm not saying that, um, you necessarily have to be material with a capital M, but I recall in one of your decisions, Judge Sloviter, you talked about the delicate evaluation of materialities is something for the trier of fact.

JUDGE SLOVITER: It sounds like my language.

JOHN COFFEY: [OVERLAPPING] The trier of fact.

JUDGE TRUMP-BARRY: That's very nice.

JOHN COFFEY: With regard to what the standard is...

JUDGE SLOVITER: Yeah, I'm trying to find out who decides -- how does one decide when a storm warning was given?

JOHN COFFEY: I believe on this record it would be the trier of fact. That you cannot say as a matter of law, given the mix of information here, the reassurances, the -- Mister, uh, Chesler called the FDA the cop on the block. Well, with regard to the warning letter, it was the advertising cop; with regard to the safety, the FDA, the cop, said, "You can go ahead and continue to sell. And, by the way, you can expand the usage. You can put the results of VIGOR on the label." And that was very reassuring. That fact alone -- now, what about the FDA warning letter, the false and misleading...? He, Mr. Chesler says there's no evidence. That's not what they say. Your Honor, the court, um, can look at the, uh, statute cited in the first paragraph of the letter and then look at the, uh, regulations. Let me just give you one example.

It says, "You have no substantial evidence." That's a magical phrase. You can't go around saying things to doctors and prescribers, people who put pills in people's mouths, unless you have substantial evidence. And there's a defined term. It means clinical studies -- um, vetted, etc. That doesn't mean that VIGOR wasn't out there and that they couldn't talk about it -- as long as they talked about both sides.

Also misleading, one example. In the FDA world, which again deals with health and failure to warn, you can have, uh, a violation. It can be false and misleading. If you say the good fact on the top and the bad fact on the bottom, not placing them close enough is false and misleading. In a securities context, that's -- that's, uh, not a claim. And, in fact, if we brought a claim -- I think I said this already...

JUDGE SLOVITER: [OVERLAPPING] Would you explain that again?

JOHN COFFEY: In other words...

JUDGE SLOVITER: What do you mean when you say...

JOHN COFFEY: [OVERLAPPING] I can give you -- the regulations are...

JUDGE SLOVITER: [OVERLAPPING] Isn't it a claim? If you say it's misleading...?

JOHN COFFEY: [OVERLAPPING] At 21 CFR 202.1 and then, um, 202.1 -- and I have a little 3-i sub-3. "Untrue or misleading information, any part of the advertisement, will not be corrected by the inclusion in another distinct part of the advertisement of a brief statement containing true information." So it's a different realm than the securities realm. And, again, it's the cop -- the safety cop, not the advertising cop, who said, "Send 100 letters to doctors and 1,000..." 'Cause one of your consultants spoke at six or seven conferences and didn't give the whole story, which by this Circuit's law, all investors were deemed to know. Now...

JUDGE TRUMP-BARRY: You would not disagree that the public record could as a matter of law show when storm warnings...?

JOHN COFFEY: I don't have a dispute with that -- that proposition.

JUDGE TRUMP-BARRY: You just say it does not show it here?

JOHN COFFEY: Here. This is so different. In NAHC the stock was down 90 percent. Not ultimately, as Mr. Chesler would suggest, but at the time this court said there were storm warnings. Benak, Your Honor found it was the Enron bankruptcy filing. I understand there was a slight distinction between of the mutual fund but -- and then in, uh, Mathews the distributions were down 60 percent. You'd never had a case where the weathermen on the scene, educated, paid to sniff out -- and I have, by the way, I have some cases for you, Judge

Roth, on analysts -- um, Hayes v. Gross on which Judge Sloviter sat, talks about market efficiency and the important role of analysts. Now, that's in the context of...

JUDGE SLOVITER: You're going to send these to us, right? If you didn't cite them.

JOHN COFFEY: Uh, I'd be happy to, um, to do that, Your Honor.

JUDGE SLOVITER: Yes. We don't want argument in a letter -- in these letters, but we want people to send us the cases so that we can read them, if they weren't in their briefs before the argument.

JUDGE ROTH: Well, this is a point that I raise. And I think it's relevant that the...

JOHN COFFEY: [OVERLAPPING] Yeah, and Burlington Coat, again, talking about market efficiency...

JUDGE ROTH: [OVERLAPPING] I think I was on that -- I think I was on that panel, as a matter of fact.

JOHN COFFEY: In light of the Harvard study, Mr. Chesler referred to the very vigorous criticism of Merck through Dr. Reicin. Well, that goes to a very important part of our argument, which is they continued to lie. We know that today. And what's really going on here, unfortunately, is, is something that this court in another context...

JUDGE TRUMP-BARRY: [OVERLAPPING] What do you mean they continued to lie?

JOHN COFFEY: Well, they continue to make false statements. If you assume what's in the complaint is true -- of course, we know more now because more continues to come out about what Merck is doing, but they knew. Our, our theory is, at the time they were putting out the Naproxen hypothesis, they knew it was wrong but there was nothing in the record before October of '03 that either -- that showed objectively that there wasn't a reasonable basis for it. So it couldn't be culpable conduct

or wrongful conduct. And there wasn't anything till October of '04 that they didn't believe it themselves.

JUDGE ROTH: But the FDA letter said it was misrepresenting? It was minimizing?

JOHN COFFEY: It was -- in advertising, in pitches to doctors that they weren't telling everybody, there was nothing new in there. And if you look at what it means to be false and misleading, it's every time you talk to a doctor about putting a pill in a patient's mouth, you need to tell them both sides of the story. That is not the standard in, in the securities context. If only it were, when it comes to notice -- but it wasn't. Mister -- they continue to -- which goes to the point about Merck continued to make statements after November 6th, 2001, new false statements. New investors purchased...

JUDGE ROTH: But after the FDA letter we knew that the agency regulating work was accusing them of making false statements every time they put forward the Naproxen hypothesis because there is no basis for it.

JOHN COFFEY: No, there was no substantial basis. But even in the arthritic committee -- the chairman of the Advisory Committee said the Naproxen hypothesis appears to be the most, the most, um, likely -- and there's, uh -- it's a very important point. The Naproxen hypothesis had plenty of support outside of Merck. Um, and at the, at the Advisory Committee meeting, um, the FDA -- one of the FDA officials, on page 1058, said, "Well, we've heard about these. There are two." That's two hypotheses. There's a Naproxen hypothesis and he says, "Merck," quote, "has put together a very strong argument in favor of that hypothesis. And there is also biological plausibility to explain that." So this wasn't...

JUDGE SLOVITER: [OVERLAPPING] But it, it distributed platelets or something...?

JOHN COFFEY: Sorry?

JUDGE SLOVITER: The fact that -- uh, the Naproxen...

JUDGE ROTH: [OVERLAPPING] It prevented coagulation.

JUDGE SLOVITER: Yeah, distributed the platelets...

JOHN COFFEY: It was -- what you read in the, the worst you read is a analyst who says, "I don't buy it." But even that analyst says, "Merck has allayed the concerns of all the other analysts." Mr. Stover -- he says that. I think it's an important enough quote to give you that - - that citation. [PAUSE] It's, uh, at A2492, after VIGOR. And, uh, he says, "Merck's analytical sequestration of heart attacks into a small retrospectively defined high-risk group proved impressionistically seductive to most Wall Street observers as far as we could see."

By the way, this is the -- this is the analyst who was the outlier, not the center -- not the center of, uh, of gravity here, and he was condemned by Merck as biased in the New York Times.

JUDGE SLOVITER: Okay, I think your time is up.

JOHN COFFEY: All right, well, thank you very much, Your Honor.

JUDGE SLOVITER: Thank you. We will take this really interesting case, once at least, under advisement.

[END OF TAPE]

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Attested to by:
Patrick Weaver

PETITIONER'S BRIEF

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No. 08-905

In the Supreme Court of the United States

MERCK & CO., INC., ET AL., PETITIONERS

v.

RICHARD REYNOLDS, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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QUESTION PRESENTED

Under 28 U.S.C. 1658(b), a plaintiff in a private securities-fraud action must file suit within two years of "the discovery of the facts constituting the violation." It is well established that the limitations period in Section 1658(b) is triggered by constructive discovery of the "facts constituting the violation," with the result that the plaintiff need not have actual knowledge of all of the relevant facts for the limitations period to begin running. It is also well established that Section 1658(b) incorporates the principle of inquiry notice, under which a plaintiff who possesses information sufficiently suggestive of wrongdoing should conduct a further inquiry to confirm the existence of his claim. The question presented is as follows:

Whether the court of appeals erred by holding that, for purposes of determining when the limitations period begins to run, a plaintiff is not on inquiry notice of a securities-fraud claim until the plaintiff possesses information, obtained without the benefit of any investigation, that the defendant acted with scienter.

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

Petitioners are Merck & Co., Inc. (Merck); and David Anstice, Lawrence A. Bossidy, William G. Bowen, Richard T. Clark, Celia Colbert, Johnnetta B. Cole, Linda M. Distlerath, Caroline Dorsa, Lloyd C. Elam, Kenneth C. Frazier, Raymond V. Gilmartin, William B. Harrison Jr., Richard C. Henriques Jr., Bernard J. Kelley, William N. Kelley, Peter S. Kim, Judy C. Lewent, Per G.H. Lofberg, Heidi G. Miller, Alise S. Reicin, Edward M. Scolnick, Thomas E. Shenk, Anne M. Tatlock, Samuel O. Thier, and Per Wold-Olsen, current or former directors, officers, or employees of Merck. Merck has no parent corporation, and no publicly held company owns 10% or more of Merck's stock. As has been reported in the news media, Merck has entered into an agreement under which, if certain conditions are met, Merck will merge with Schering-Plough Corporation; that merger has not yet been consummated.

Respondents are Richard Reynolds; Jan Charles Finance S.A.; Park East, Inc.; Public Employees' Retirement System of Mississippi; Union Asset Management Holding AG; Loren Arnoff; Robert Edwin Burns; Joseph S. Fisher; Joseph Goldman; Jerome Haber; Rhoda Kanter; Sherrie B. Knuth; Steven LeVan; Martin Mason; Marc Nathanson; Naomi Raphael; Frank H. Saccone; Charlotte Savarese; and Joe Savarese.

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In the Supreme Court of the United States

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MERCK & CO., INC., ET AL., PETITIONERS

v.

RICHARD REYNOLDS, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
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BRIEF FOR THE PETITIONERS

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-61a) is reported at 543 F.3d 150. The opinion of the district court (Pet. App. 62a-99a) is reported at 483 F. Supp. 2d 407.

JURISDICTION

The judgment of the court of appeals was entered on September 9, 2008. A petition for rehearing was denied on October 17, 2008 (Pet. App. 100a-101a). The petition for a writ of certiorari was filed on January 15, 2009, and granted on May 26, 2009. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISION INVOLVED

In relevant part, 28 U.S.C. 1658(b) provides:

> [A] private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws * * * may be brought not later than the earlier of—
> (1) 2 years after the discovery of the facts constituting the violation; or
> (2) 5 years after such violation.

STATEMENT

Petitioners are Merck & Co., Inc. (Merck), and several of its current and former directors, officers, and employees; respondents are purchasers of Merck stock. Beginning on November 6, 2003, various plaintiffs brought sixteen actions against Merck in federal district courts, claiming, *inter alia*, that Merck had engaged in securities fraud in violation of Section 10(b) of the Securities Exchange Act of 1934 (1934 Act), 15 U.S.C. 78j(b), and Rule 10b-5 thereunder, 17 C.F.R. 240.10b-5. The Judicial Panel on Multidistrict Litigation transferred those actions filed in other districts to the District of New Jersey, and respondents subsequently filed a consolidated amended class-action complaint against Merck and the individual petitioners. As is relevant here, petitioners moved to dismiss respondents' securities-fraud claim on the ground that it was time-barred because respondents were on inquiry notice of that claim before November 6, 2001—*i.e.*, more than two years before the initial version of their complaint was filed. The district court granted petitioners' motion to dismiss, Pet. App. 62a-99a, but a divided court of appeals reversed and remanded, *id.* at 1a-61a.

1. Merck is one of the Nation's largest pharmaceutical companies. In the mid-1990s, Merck developed Vioxx, one of a class of anti-inflammatory medicines known as "COX-2 inhibitors." As the name suggests, COX-2 inhibitors selectively inhibit the production of an enzyme known as cyclooxygenase-2 (COX-2), which is involved in the body's generation of pain and inflammation. By contrast, other anti-inflammatory medicines such as aspirin, ibuprofen, and naproxen operate by inhibiting the production not only of COX-2, but also of cyclooxygenase-1 (COX-1), which protects the lining of the gastrointestinal tract. The inhibition of COX-1 can lead to serious, even fatal, gastrointestinal problems. Because COX-2 inhibitors such as Vioxx have no significant effect on COX-1, their development was viewed as an important milestone in the management of both chronic and acute pain. In May 1999, the Food and Drug Administration (FDA) approved Vioxx for various prescription uses, and Merck brought Vioxx to market. Pet. App. 5a, 64a.

Even after FDA's initial approval, Merck continued to conduct extensive studies of Vioxx's safety and efficacy. From January 1999 to March 2000, Merck conducted the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, which examined the comparative gastrointestinal safety of Vioxx and naproxen. The VIGOR study confirmed that patients on Vioxx had a lower rate of gastrointestinal events, but also indicated that those patients had a higher rate of certain cardiovascular events. One possible explanation for the latter disparity was that, when taken in a particular manner, naproxen inhibited platelet aggregation, prevented blood clots, and thus lowered the risk of those cardiovascular events; this theory came to be known as the "naproxen hypothesis." Another possible explanation was that Vioxx somehow increased the potential for blood clots. On March 27,

2000, Merck announced the preliminary results of the VIGOR study. In a press release, Merck noted the disparity in cardiovascular events and stated that the disparity was "consistent with naproxen's ability to block platelet aggregation." At the same time, Merck acknowledged that "[t]his effect * * * had not been observed previously in any clinical studies for naproxen." J.A. 291; Pet. App. 5a-7a, 64a-65a.

In the wake of the VIGOR study, there was extensive public debate about the competing explanations for the disparity in cardiovascular events. For example, on April 27, 2000, Reuters reported that at least one analyst "was not reassured by Merck's suggestion that naproxen conferred protection against heart attacks and strokes." On February 8, 2001, FDA's Arthritis Advisory Committee held a public hearing to discuss the safety of Vioxx, which provoked a wave of articles in the news media. The following day, USA Today reported that "[a]rthritis patients who take Vioxx * * * should know that the blockbuster drug might increase their risk of suffering a heart attack." And on August 22, 2001, the Journal of the American Medical Association (JAMA) published an article reporting that available data raised a "cautionary flag" about the possibility that COX-2 inhibitors such as Vioxx were linked to an increased risk of cardiovascular events. The JAMA article provoked another wave of articles in the news media. J.A. 319, 332, 358, 362, 413; Pet. App. 7a-11a, 65a-71a.

Consistent with its initial press release announcing the preliminary results of the VIGOR study, Merck continued to express its belief that the "likely" explanation for the disparity in cardiovascular events was that naproxen prevented blood clots. On September 17, 2001, however, FDA issued a "Warning Letter" to Merck in which it charged that Merck had "engaged in a promo-

tional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the [VIGOR] study, and thus, misrepresents the safety profile for Vioxx." FDA contended that, "[a]lthough the exact reason for the increased rate of [cardiovascular events] observed in the Vioxx treatment group is unknown," Merck had "selectively present[ed] [a] hypothetical explanation for the observed increase": namely, that "Vioxx does not increase the risk of [cardiovascular events] and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation." FDA acknowledged that "[t]hat is a possible explanation," but alleged that Merck had "fail[ed] to disclose that [its] explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic [*i.e.*, clot-promoting] properties." The letter demanded that Merck cease the cited promotional activities and issue a corrective letter. J.A. 339, 340, 352-353.

FDA posted the warning letter on its website on Friday, September 21, 2001. In the following days, the letter received extensive coverage in the news media. On September 24, Reuters reported that "U.S. regulators have charged [Merck] with misleading doctors about its blockbuster painkiller Vioxx with promotions that downplayed a possible risk of heart attacks." And on September 25, the Wall Street Journal reported that "[f]ederal regulators warned [Merck] for improper marketing of its blockbuster arthritis drug Vioxx, saying the company had misrepresented the drug's safety profile and minimized its potential risks." The article further noted that, "[w]hile the FDA sends out dozens of routine citations annually, it issues only a handful of these more-serious warning letters each year." J.A. 482, 494; Pet. App. 11a-15a, 71a-75a.

Even before the release of the FDA warning letter, various plaintiffs had begun to file lawsuits alleging that Merck had made misstatements concerning the cardiovascular risks associated with Vioxx. On May 29, 2001, a group of plaintiffs filed a product-liability class action against Merck in the United States District Court for the Eastern District of New York, alleging that "users of Vioxx were four times as likely to suffer heart attacks as compared to [users of] other less expensive medications" but that Merck had "taken no affirmative steps to communicate this critical information to class members." J.A. 868, 869; Pet. App. 10a, 76a.

In the immediate aftermath of the FDA warning letter, several additional suits were filed. On September 27, 2001, a group of plaintiffs filed a consumer-fraud class action against Merck in New Jersey state court, relying on the FDA warning letter and alleging that Merck "omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Vioxx" and that Merck "purposefully downplayed and/or understated the serious nature of the risks associated with Vioxx." On September 28, a group of plaintiffs filed a product-liability and consumer-fraud action against Merck in Utah state court, also relying on the FDA warning letter and alleging that Merck had "misrepresented that Vioxx was * * * safe and effective * * * when in fact the drug causes serious medical problems such as an increased risk of cardiovascular events." And on October 1, a plaintiff filed a product-liability action against Merck in Alabama state court, alleging that Merck had failed to disclose that "Vioxx causes heart attacks." J.A. 885, 893, 910-911, 949, 954; Pet. App. 15a, 77a-78a.

On October 9, 2001—still more than two years before the initial version of the complaint at issue here was

filed—the New York Times published a lengthy article entitled, "For Pain Reliever, Questions of Risk Remain Unresolved." That article reported on the FDA warning letter and noted that "some heart specialists say they are now telling patients that they may want to consider taking other drugs for pain." The article quoted Dr. Edward Scolnick, a petitioner in this case and then-president of Merck Research Laboratories, as stating that "[t]here are two possible interpretations" of the data indicating the disparity in cardiovascular events and that none of the findings to date had been sufficient to prove that the issue was fully resolved. J.A. 502, 503, 504-505; Pet. App. 15a-17a, 75a-76a.

2. On November 6, 2003—shortly after a disappointing earnings report that caused Merck's stock price to drop considerably—a plaintiff filed a class action against Merck in the United States District Court for the Eastern District of Louisiana. See Pet. App. 18a. The plaintiff in that action claimed, *inter alia*, that Merck had made fraudulent misstatements and omissions concerning Vioxx, in violation of Section 10(b) of the 1934 Act and Rule 10b-5 thereunder.

After the initial complaint was filed, study data indicated that certain patients taking Vioxx for prolonged periods had a higher rate of cardiovascular events relative to patients taking a placebo. On September 30, 2004, promptly after learning of the data, Merck withdrew Vioxx from sale. Pet. App. 18a-19a, 78a-79a. Both before and after the withdrawal, various plaintiffs filed fifteen other federal securities-fraud actions against Merck. The Judicial Panel on Multidistrict Litigation then transferred the securities-fraud actions filed in other districts to the District of New Jersey. See J.A. 15-19.

On June 14, 2005, respondents filed a consolidated amended class-action complaint in the District of New

Jersey against Merck and the individual petitioners, claiming, *inter alia*, that Merck and some of the individual petitioners had engaged in securities fraud in violation of Section 10(b). See J.A. 20-264 (Fourth Amended Complaint). Respondents alleged that the identified petitioners had "made a series of materially false and misleading statements and omissions concerning * * * the safety profile of Merck's prescription painkilling drug VIOXX": specifically, by "concealing and minimizing the significantly increased risk of heart attacks in patients taking the drug." J.A. 24, 26.

As is relevant here, petitioners moved to dismiss respondents' securities-fraud claim based on the statute of limitations.[1] A plaintiff in a private securities-fraud action must file suit within two years of "the discovery of the facts constituting the violation." 28 U.S.C. 1658(b). Petitioners contended that respondents' claim was time-barred because respondents were on inquiry notice of that claim before November 6, 2001—*i.e.*, more than two years before the initial version of the complaint was filed.

The district court granted petitioners' motion to dismiss. Pet. App. 62a-99a. The court reasoned that, in order to have inquiry notice of a securities-fraud claim, "plaintiffs need not have actual knowledge or know all of the details of the alleged fraud to trigger the limitations period." *Id.* at 83a. Instead, a plaintiff need only possess

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[1] In addition to their securities-fraud claim, respondents brought numerous claims under other provisions of the Securities Act of 1933 and the 1934 Act, see J.A. 252-261; petitioners also moved to dismiss those claims based on the applicable statutes of limitations. The district court held that all of respondents' claims were time-barred. See Pet. App. 98a-99a. In reversing the district court, the court of appeals specifically addressed the timeliness only of respondents' securities-fraud claim. See *id.* at 46a, 48a n.17.

enough information to "alert a reasonable person to the probability that misleading statements or significant omissions had been made." *Id.* at 83a-84a (internal quotation marks and citation omitted). Once a plaintiff is on inquiry notice, the court continued, "plaintiffs have an obligation to investigate the basis for their claims." *Id.* at 84a. Specifically, "plaintiffs must show that they undertook their duty to investigate the basis for their claims but nevertheless failed to discover information necessary to initiate a securities fraud action." *Ibid.* If a plaintiff "[c]hoos[es] not to investigate," he will be deemed to have discovered his claim as of the date of inquiry notice. *Ibid.*

Applying that standard, the district court held that respondents were on inquiry notice of their securities-fraud claim by no later than October 9, 2001, the date of the New York Times article. Pet. App. 84a-98a. In so holding, the court first focused on the FDA warning letter. *Id.* at 85a-86a. The court noted that the warning letter "charges Merck with engaging in deceptive and misleading conduct with regard to the safety profile of VIOXX," *id.* at 85a, and that "the accusations in the Warning Letter have particularly strong impact in light of the fact that they are leveled by Merck's principal regulator," *id.* at 86a. The court determined that "[a] reasonable investor in Merck would have discovered this public, company-specific information and recognized it as a storm warning of fraud." *Ibid.*

The district court explained that it "might arguably conclude that the FDA Warning Letter alone [was] sufficient to put [respondents] on inquiry notice of their claims against Merck." Pet. App. 86a. The court reasoned, however, that it "need not make that conclusion, because the FDA Warning Letter was not issued in a vacuum of information." *Id.* at 87a. The court noted that

"information raising at the very least doubts as to the safety profile of VIOXX accumulated in the public realm prior to the issuance of the Warning Letter" and that "[p]ublic discussion of possible troubles at Merck continued, and it may even be said intensified[,] immediately following the publication of the Warning Letter." *Id.* at 88a. The court also cited the initiation of other Vioxx-related lawsuits. *Id.* at 89a. While acknowledging that those suits "plead for relief under different legal theories than those at issue here," the court observed that "the lawsuits are predicated upon the same alleged wrongdoing." *Ibid.* Based on all of the foregoing information, the district court stated that "the torrent of publicity" concerning Vioxx was "more akin to thunder, lightning and pouring rain than subtle warnings of a coming storm," *id.* at 94a, and determined that "it is clear that storm warnings of fraud by the company existed more than two years before this Complaint was filed," *id.* at 97a.

The district court noted that respondents "have not argued that they conducted a diligent investigation" and that "nothing in the Complaint demonstrates that they were unable to uncover pertinent information during the limitations period." Pet. App. 98a. For that reason, the court concluded that the limitations period was triggered as of the date of inquiry notice, and that respondents' securities-fraud claim was therefore time-barred. *Ibid.*

3. A divided court of appeals reversed and remanded. Pet. App. 1a-61a.

a. The court of appeals first explained that "[w]hether the plaintiffs, in the exercise of reasonable diligence, should have known of the basis for their claims depends on whether they had sufficient information of possible wrongdoing to place them on inquiry notice or to excite storm warnings of culpable activity." Pet. App. 22a (internal quotation marks and citation omitted). If

they did, "the burden shifts to the plaintiffs to show that they exercised reasonable due diligence and yet were unable to discover their injuries." *Ibid.* (internal quotation marks and citation omitted). Critically for present purposes, the court took the position that, "to trigger storm warnings of culpable activity in the context of a claim alleging falsely-held opinions or beliefs, investors must have sufficient information to suspect that the defendant engaged in culpable activity, i.e., that they did not hold those opinions or beliefs in earnest." *Id.* at 33a (internal quotation marks and citation omitted).

Applying that standard, the court of appeals held that the district court had erred by determining that respondents were on inquiry notice by no later than October 9, 2001. Pet. App. 35a-47a. The court of appeals suggested that the FDA warning letter was insufficient to place respondents on inquiry notice. *Id.* at 42a-45a. The court reasoned that "FDA was acting as a regulator of drug advertising, rather than as a regulator of the securities markets," *id.* at 42a, and that "FDA did not charge that the naproxen hypothesis was wrong" but instead "simply directed Merck to be more clear about the widely known alternative hypothesis," *id.* at 43a. The court of appeals also discounted the district court's reliance on the filing of other lawsuits challenging the accuracy of Merck's representations concerning Vioxx. *Id.* at 45a. The court of appeals noted that "none of th[o]se lawsuits alleged securities fraud" and that "[t]he claims in those lawsuits alleged that Merck failed to provide publicly available information to Vioxx consumers, rather than to Merck investors." *Ibid.*

b. Judge Roth dissented. Pet. App. 49a-61a. She agreed with the district court that " 'storm warnings' alerting a reasonable investor of *possible* culpable activity on the part of Merck were evident more than two

years prior to the filing of [respondents'] complaint." *Id.* at 49a. Judge Roth explained that "any reasonable investor reading the [FDA] warning letter could see the problem with Vioxx": *viz.*, "the 'possibility' that Merck had fraudulently misrepresented the cardiovascular safety of its 'blockbuster' product." *Id.* at 51a. She added that, "[i]n response to the FDA's warning letter, there was widespread media and financial analyst coverage commenting on the FDA's charges against Merck." *Id.* at 56a. And she noted the filing of other lawsuits, observing that "the general allegations contained within these complaints relating to Merck's intentional misrepresentation with regard to Vioxx's safety similarly formed the basis of [respondents'] complaint." *Id.* at 58a. Because respondents did not contend that they had conducted a diligent investigation, Judge Roth would have concluded that the limitations period was triggered as of the date of inquiry notice, and that respondents' securities-fraud claim was therefore time-barred. *Id.* at 61a.

c. Petitioners filed a petition for panel rehearing, which was denied by a 2-1 vote, and a petition for rehearing en banc, which was denied by a 6-4 vote. Pet. App. 100a-101a. Judge Roth would have granted panel rehearing, and Judges Rendell, Ambro, Fuentes, and Jordan would have granted rehearing en banc. *Id.* at 101a.[2]

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[2] On remand, respondents filed another amended version of their complaint. See J.A. 270-290 (Fifth Amended Complaint). Petitioners then moved to dismiss the amended complaint on the grounds, *inter alia*, that respondents had failed either to allege an actionable misstatement or omission or to allege facts sufficient to permit a strong inference that petitioners acted with scienter. See J.A. 11-14. The district court has stayed proceedings on remand pending this Court's decision. See J.A. 14.

SUMMARY OF ARGUMENT

A. The court of appeals erred by holding that, for purposes of determining when the limitations period begins to run, a plaintiff is not on inquiry notice of a securities-fraud claim until the plaintiff possesses information that the defendant acted with scienter.

Under 28 U.S.C. 1658(b), a plaintiff in a private securities-fraud action must file suit within two years of "the discovery of the facts constituting the violation." As a preliminary matter, lower courts have consistently held, and Congress ratified the understanding, that the limitations period for securities-fraud claims is triggered by constructive discovery of the "facts constituting the violation": *i.e.*, when the plaintiff *should have* known of the relevant facts, even if he did not *actually* know of those facts until a later date.

It is similarly well established that the discovery rule for securities-fraud claims incorporates the principle of inquiry notice. Under that principle, a court must determine when the plaintiff possessed sufficient information to cause him to suspect the possibility that the defendant has engaged in wrongdoing, so as to trigger a duty to investigate further to confirm the existence of his claim. In order to satisfy the standard for inquiry notice, a plaintiff need not possess information specifically bearing on each and every element of the underlying violation. That general rule is equally, if not more, applicable in the context of securities-fraud claims. When a plaintiff has reason to believe that a defendant has made a material misstatement or omission in connection with the purchase or sale of a security, the plaintiff ordinarily should at least suspect the possibility that the defendant did so with scienter and therefore committed securities fraud. The court of appeals' contrary rule is entirely

without foundation, and, if adopted, it would essentially render the principle of inquiry notice a dead letter.

Under the correct legal standard, respondents were on inquiry notice of their claim more than two years before the initial version of the complaint was filed, because they possessed considerable information suggesting the possibility that petitioners had engaged in securities fraud in connection with their statements concerning Vioxx. Indeed, even under the court of appeals' more liberal standard, respondents were on inquiry notice, because they also possessed information specifically suggesting the possibility that petitioners had made misstatements with scienter.

B. In order to answer the question presented and reverse the judgment below, the Court need only agree that the court of appeals erred by holding that a securities-fraud plaintiff is not on inquiry notice until he possesses information that the defendant acted with scienter. The Court, however, may also wish to address the broader issue of how the date on which a plaintiff is placed on inquiry notice affects the running of the statute of limitations. If it does, it should hold that, at least where, as here, the plaintiff fails to conduct a reasonably diligent investigation after being placed on inquiry notice of a potential violation, the limitations period begins to run from the date of inquiry notice.

There is substantial support for the position that the limitations period always begins to run from the date of inquiry notice, such that a plaintiff must conduct the inquiry contemplated by the doctrine of inquiry notice during the limitations period itself. That approach would be relatively straightforward in its application, because there will often be a particular event that unambiguously places a plaintiff on inquiry notice. The language of Section 1658(b), moreover, supports such an approach,

because the better view is that the phrase "facts constituting the violation" does not encompass the fact of scienter. And even if it did, a plaintiff who is on inquiry notice could be deemed, as a constructive matter, to have "discover[ed] * * * the facts constituting the violation," without possessing information specifically bearing on each and every element of the violation.

At most, when a securities-fraud plaintiff is on inquiry notice of his claim, the plaintiff should be entitled to an additional period of time before the limitations period commences only when he conducts a reasonably diligent investigation. That approach readily comports both with the language of Section 1658(b) and with this Court's discovery-rule jurisprudence, which makes clear that the discovery rule incorporates the equitable principle that a plaintiff must exercise due diligence in discovering the alleged violation. And it strikes a reasonable balance between defendants' interest in repose and plaintiffs' interest in remediation, because it creates appropriate incentives for plaintiffs to investigate potential claims upon being placed on inquiry notice.

Petitioners would prevail under the foregoing approach, because respondents have never argued, in response to petitioners' limitations defense, that they undertook *any* investigation after being placed on inquiry notice. Should the Court reach the broader issue concerning the running of the statute of limitations, therefore, it should hold that the limitations period began running in this case once respondents were on inquiry notice, and that their securities-fraud claim was therefore untimely.

ARGUMENT

THE COURT OF APPEALS ERRED BY HOLDING THAT RESPONDENTS' SECURITIES-FRAUD CLAIM WAS TIMELY UNDER 28 U.S.C. 1658(b)

A. Respondents Were On Inquiry Notice Of Their Securities-Fraud Claim More Than Two Years Before The Initial Version Of The Complaint Was Filed

1. The Limitations Period Of Section 1658(b) Is Triggered By Constructive, As Well As Actual, Discovery Of The "Facts Constituting The Violation"

a. Statutes of limitations "are found and approved in all systems of enlightened jurisprudence." *Wood* v. *Carpenter*, 101 U.S. 135, 139 (1879). Such statutes "represent a pervasive legislative judgment that it is unjust to fail to put the adversary on notice to defend within a specified period of time and that the right to be free of stale claims in time comes to prevail over the right to prosecute them." *United States* v. *Kubrick*, 444 U.S. 111, 117 (1979) (internal quotation marks and citation omitted).

Ordinarily, the limitations period "begins to run[] at the time of the occurrence of a judicially recognizable injury or event constituting a breach of duty," even if "the plaintiff is unaware of the accrual of his or her cause of action." 2 Calvin W. Corman, *Limitation of Actions* § 11.1.1, at 134 (1991) (Corman). In some circumstances, however, the limitations period does not run from the date of accrual, but is instead subject to the "discovery rule": *viz.*, the rule that the limitations period begins to run when a plaintiff discovers, or should discover, facts that form the basis of the plaintiff's cause of action. That rule originated at equity, and this Court has long recognized its applicability to fraud claims. See, *e.g.*, *Bailey* v. *Glover*, 88 U.S. (21 Wall.) 342, 348 (1875). Numerous federal statutes of limitations now expressly incorporate

the discovery rule in some form, and this Court has recognized that the discovery rule also applies in certain circumstances in which the relevant statute of limitations does not include one. See *TRW Inc.* v. *Andrews*, 534 U.S. 19, 27 (2001) (citing cases).

b. This case concerns the limitations period for a private action under Section 10(b) of the Securities Exchange Act of 1934. That act contained no statute of limitations for private claims under Section 10(b), for the simple reason that it did not provide for private claims in the first place; the private cause of action under Section 10(b), famously, is a "judicial construct." *Stoneridge Inv. Partners, LLC* v. *Scientific-Atlanta, Inc.*, 128 S. Ct. 761, 772 (2008).

Accordingly, in *Lampf, Pleva, Lipkind, Prupis & Petigrow* v. *Gilbertson*, 501 U.S. 350 (1991), this Court undertook "the awkward task of discerning the limitations period that Congress intended courts to apply to a cause of action it really never knew existed." *Id.* at 359. The Court noted that the 1934 Act contained a number of limitations provisions governing its express causes of action and that almost all of those provisions contained "some variation of a 1-year period after discovery combined with a 3-year period of repose." *Id.* at 359-360. Observing that those provisions "differ[ed] slightly in terminology," the Court ultimately selected, as the applicable limitations provision, the provision governing claims of market manipulation under Section 9 of the 1934 Act. *Id.* at 364 n.9. That provision requires that a plaintiff file suit "within one year after the discovery of the facts constituting the violation and within three years after such violation." 1934 Act § 9(e), 15 U.S.C. 78*i*(e).

In 2002, as part of the Corporate and Criminal Fraud Accountability Act, Pub. L. No. 107-204, 116 Stat. 800 (Sarbanes-Oxley Act), Congress for the first time ex-

pressly provided a statute of limitations for Section 10(b) claims. See 28 U.S.C. 1658(b). In so doing, Congress codified the limitations provision previously set out in Section 9(e) of the 1934 Act and adopted by this Court in *Lampf*, with only one modification: Congress extended the limitations and repose periods to two years and five years, respectively. See *ibid.*

c. The limitations period in Section 1658(b) runs from the date of "discovery of the facts constituting the violation." It is well established—and has never been disputed in this case—that the limitations period in Section 1658(b) is triggered not only by *actual* discovery of the "facts constituting the violation," but also by *constructive* discovery: *i.e.*, where the plaintiff should have known of the relevant facts at an earlier date than he actually did.

Because the discovery rule is fundamentally an equitable principle, the default understanding has always been that, when a statute of limitations either explicitly or implicitly incorporates the discovery rule, the limitations period begins to run from the date of either actual or constructive discovery. See, *e.g.*, *Kirby* v. *Lake Shore & Mich. S. R.R. Co.*, 120 U.S. 130, 138 (1887); *Wood*, 101 U.S. at 143; *Stearns* v. *Page*, 48 U.S. (7 How.) 819, 829 (1849). Congress acted against the backdrop of that default understanding when it enacted the various limitations provisions in the 1934 Act—including, most importantly, the limitations provision in Section 9(e), which served as the model for Section 1658(b). In the wake of *Lampf*, moreover, courts of appeals applying the Section 9(e) limitations provision in the context of Section 10(b) actions consistently held that the limitations period begins to run from the date of constructive, as well as actual, discovery, notwithstanding the absence of any express language in Section 9(e) to that effect. See, *e.g.*,

Great Rivers Coop. of S.E. Iowa v. *Farmland Indus., Inc.*, 120 F.3d 893, 896 (8th Cir. 1997); *Law* v. *Medco Research, Inc.*, 113 F.3d 781, 785 (7th Cir. 1997); *Howard* v. *Haddad*, 962 F.2d 328, 330 (4th Cir. 1992) (Powell, J.).

By leaving intact the relevant language from Section 9(e) in enacting Section 1658(b), Congress ratified the settled understanding that the language encompassed constructive discovery. See, *e.g.*, 148 Cong. Rec. 12,502 (2002) (statement of Sen. Leahy) (noting that Section 1658(b) would not "chang[e] the basic standards of the law," apart from lengthening the limitations period). The limitations period under Section 1658(b) thus begins to run once a plaintiff has either actually or constructively "discover[ed] the facts constituting the violation." The issues in this case center on the circumstances under which constructive discovery can be said to have occurred, such that the limitations period is triggered.

2. *To Be On Inquiry Notice Of A Claim For Purposes Of The Discovery Rule In Section 1658(b), A Plaintiff Need Not Possess Information That The Defendant Acted With Scienter*

The court of appeals held in this case that, for purposes of the discovery rule in Section 1658(b), a plaintiff in a private securities-fraud action is not on inquiry notice of his claim until the plaintiff possesses information that the defendant acted with scienter. Pet. App. 33a.[3]

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[3] See *Alaska Elec. Pension Fund* v. *Pharmacia Corp.*, 554 F.3d 342, 348 (3d Cir. 2009) (confirming that the court of appeals' decision in this case stands for the proposition that "inquiry notice, in securities fraud suits, requires storm warnings indicating that defendants acted with scienter"), petition for cert. pending, No. 08-1315 (filed Apr. 22, 2009). That proposition, moreover, was at the heart of respondents' argument below. See, *e.g.*, Resp. C.A. Br. 31.

Assuming, *arguendo*, that scienter is one of the "facts constituting the violation" for purposes of Section 1658(b), but see pp. 41-42, *infra*, the court of appeals' holding was erroneous, and its error warrants reversal.

a. It is well established—and, again, has never been disputed in this case—that the discovery rule in Section 1658(b) incorporates the principle of inquiry notice. That principle is best understood as a refinement of the principle of constructive discovery, and it has deep roots in the application of the discovery rule to fraud claims more generally. See, *e.g.*, *Wood*, 101 U.S. at 141; *Burke* v. *Smith*, 83 U.S. (16 Wall.) 390, 401 (1873). In the wake of *Lampf*, those courts of appeals that addressed the issue had consistently held that the Section 9(e) limitations provision, as applied to Section 10(b) actions, incorporated not only the broader principle of constructive discovery, but also the principle of inquiry notice, see, *e.g.*, *Berry* v. *Valence Tech., Inc.*, 175 F.3d 699, 703-704 (9th Cir.) (citing cases), cert. denied, 528 U.S. 1019 (1999), and Congress ratified that understanding in enacting Section 1658(b), see, *e.g.*, S. Rep. No. 146, 107th Cong., 2d Sess. 29 (2002) (additional views of eight Senators).

As the name suggests, the basic premise underlying the doctrine of inquiry notice is that there comes a point at which a plaintiff possesses a quantum of information sufficiently suggestive of wrongdoing that he should conduct a further inquiry to confirm the existence of his claim: that is, where, "when judged objectively[,] the plaintiff should be on notice that further inquiry is needed." 2 Corman § 11.5.8, at 203. Rather than more generally determining when a hypothetical plaintiff should have discovered the facts giving rise to his claim, a court applying the doctrine of inquiry notice determines when there was sufficient information available to the plaintiff so as to trigger the duty to investigate fur-

ther. In the context of securities-fraud claims governed by Section 1658(b), the lower courts have held that a plaintiff is on inquiry notice when he receives so-called "storm warnings": *i.e.*, when there was sufficient information in the plaintiff's possession, or in the public domain, to cause a reasonable investor to suspect the possibility that the defendant has engaged in securities fraud. See, *e.g.*, *Benak* v. *Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 400 (3d Cir. 2006); *Sterlin* v. *Biomune Sys.*, 154 F.3d 1191, 1196 (10th Cir. 1998); *Jensen* v. *Snellings*, 841 F.2d 600, 607 (5th Cir. 1988).[4]

b. It necessarily follows from the standard for inquiry notice that, in order to possess sufficient information to suspect the possibility that the defendant has engaged in wrongdoing, a plaintiff need not possess information specifically bearing on each and every element of the underlying violation. Indeed, this Court has already recognized that principle, if implicitly. In *TRW*, the Court considered whether to read the discovery rule into the then-applicable version of the statute of limitations for claims under the Fair Credit Reporting Act. See 534 U.S. at 22-23. The Court ultimately refused to do so. See *id.* at 33. Critically for present purposes, however, the Court acknowledged that, if the discovery rule had been applicable, a plaintiff could be on inquiry notice when the plaintiff had been denied credit but did not

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[4] The Second Circuit has formulated the standard in terms of whether the plaintiff possessed sufficient information to suggest that it was *probable* that the defendant had engaged in securities fraud. See, *e.g.*, *Newman* v. *Warnaco Group, Inc.*, 335 F.3d 187, 193 (2d Cir. 2003). It is questionable, however, whether that slightly different formulation would lead to substantially different results in practice, and respondents do not contend otherwise. See Br. in Opp. 16 n.6.

possess information that a credit agency had made improper disclosures, unless the defendant had engaged in fraudulent concealment that would render discovery of the improper disclosures impossible (and, in the Court's view, would thus delay the running of the limitations period). See *id.* at 30-31. The Court therefore recognized that a plaintiff could be on inquiry notice without possessing information specifically relating to each element—even an essential element—of the violation.

That general rule is equally, if not more, applicable in this context. When a plaintiff has reason to believe that a defendant has made a material misstatement or omission in connection with the purchase or sale of a security, the plaintiff ordinarily should at least *suspect the possibility* that the defendant did so with scienter and therefore committed a violation of Section 10(b)—even if it is also possible that the misstatement is susceptible of an innocent explanation. That is particularly true because, as this Court has recognized, scienter in securities-fraud actions is usually proved through inferences from circumstantial evidence. See, *e.g.*, *Herman & MacLean* v. *Huddleston*, 459 U.S. 375, 390 n.30 (1983). In many cases, when a plaintiff possesses information suggesting that the defendant has made a misstatement, the plaintiff will rely on the same information to support the inference that the defendant has made the misstatement intentionally or recklessly. See, *e.g.*, *Makor Rights & Issues Ltd.* v. *Tellabs Inc.*, 513 F.3d 702, 709 (7th Cir. 2008). Insofar as the two categories of information may not always be readily distinguishable, there is all the more reason to question the court of appeals' bright-line rule that a plaintiff who possesses information that the defendant made a misstatement can *never* be on inquiry notice until he also possesses discrete information specifically relating to scienter.

The court of appeals' rule is flawed for the additional reason that it would threaten to eliminate the principle of inquiry notice altogether. Under the court of appeals' rule, a plaintiff would not be on inquiry notice until he possesses information specifically relating to all of the elements of the violation, including scienter. A plaintiff who possesses such information, however, could at that point be said to have *discovered* his claim, even if he does not yet possess the facts to a sufficient level of detail to be able to file a complaint. See pp. 28-33, *infra*. Under the court of appeals' rule, therefore, the doctrine of inquiry notice would effectively do no work, because a plaintiff would not "ha[ve] * * * storm warnings until the hurricane makes landfall." *Betz* v. *Trainer Wortham & Co.*, 519 F.3d 863, 869 (9th Cir. 2008) (Kozinski, C.J., dissenting from denial of rehearing en banc), petition for cert. pending, No. 07-1489 (filed May 27, 2008).

c. Not only is there no logical basis for the court of appeals' rule, but there is also no support for it in the law. As a preliminary matter, at the time Congress enacted Section 1658(b), two courts of appeals had squarely held that a plaintiff need not possess information that the defendant acted with scienter in order to be on inquiry notice, see *Theoharous* v. *Fong*, 256 F.3d 1219, 1228 (11th Cir. 2001); *Sterlin*, 154 F.3d at 1203, and numerous other courts of appeals had held that the limitations period for Section 10(b) actions incorporates the principle of inquiry notice without additionally requiring the plaintiff to possess information specifically relating to scienter, see *Berry*, 175 F.3d at 703-704 (citing cases). The only two circuits to have adopted the rule that a plaintiff must possess information specifically relating to scienter in order to be on inquiry notice—the Third Circuit in this case and the Ninth Circuit in *Trainer Wortham*—have done so only very recently, years after

Congress enacted Section 1658(b). It is therefore reasonable to assume that, while Congress ratified the doctrine of inquiry notice in enacting Section 1658(b), see p. 20, *supra*, it did not intend to adopt any more particular requirement that a plaintiff possess information relating to scienter in order to be on inquiry notice.

There is also no support for the court of appeals' rule in the considerable body of state law applying the doctrine of inquiry notice in the context of fraud claims. Although the law in some States with regard to fraud claims is not entirely clear, the great majority of the States apply discovery rules that incorporate the principle of inquiry notice; in many of those States, moreover, the limitations period is expressly triggered by discovery of the "facts constituting the fraud." See, *e.g.*, Cal. Civ. Proc. Code § 338(d) (West 2006); Mont. Code Ann. § 27-2-203 (2007); N.D. Cent. Code § 28-01-16(6) (2009).

In those States that apply the traditional discovery rule in some form, we are not aware of a single case in which a court has adopted the rule that a plaintiff in a fraud action is not on inquiry notice of his claim until he possesses information that the defendant acted with scienter.[5] To the contrary, some courts have expressly rejected the proposition that a plaintiff must possess information that the defendant acted with scienter in order to be on inquiry notice. See, *e.g.*, *Breitz* v. *Lykes-Pasco Packing Co.*, 561 So. 2d 1204, 1205 (Fla. Dist. Ct. App. 1990); *Stroh Die Casting Co.* v. *Monsanto Co.*, 502 N.W.2d 132, 143 n.18 (Wis. Ct. App. 1993). In addition,

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[5] The case that comes closest to imposing such a requirement is *City of Fairbanks* v. *Amoco Chemical Co.*, 952 P.2d 1173 (Alaska 1998). That case, however, involved a limitations period that was triggered only by *actual* discovery. *Id.* at 1178.

numerous other courts have implicitly rejected that proposition, by holding that a plaintiff was on inquiry notice without specifically identifying information relating to scienter. See, *e.g.*, *Blegen* v. *Monarch Life Ins. Co.*, 365 N.W.2d 356, 357 (Minn. Ct. App. 1985); *Wise* v. *Anderson*, 359 S.W.2d 876, 879 (Tex. 1962); *Hansen* v. *Stanley Martin Cos.*, 585 S.E.2d 567, 574-575 (Va. 2003).

d. The court of appeals' rule is similarly in tension with this Court's decisions concerning the discovery rule more generally. In those decisions, the Court has routinely adopted interpretations of the discovery rule that do not require a plaintiff to discover all of the elements of his claim before the limitations period begins running. For similar reasons, when the principle of inquiry notice is applicable, a plaintiff need not possess information specifically relating to each element of his claim to trigger the duty of further investigation.

In *Kubrick*, the plaintiff in a medical-malpractice action under the Federal Tort Claims Act (FTCA) argued that the limitations period should begin to run only once the plaintiff possessed (or should have possessed) knowledge that the prior medical treatment that had caused his injury was negligent. 444 U.S. at 116. The Court rejected that argument. *Id.* at 125. Although the Court did not explicitly advert to the principle of inquiry notice, it effectively framed its analysis in inquiry-notice terms. Specifically, the Court noted that, once a plaintiff had discovered the "critical facts" of his injury and the cause, the plaintiff "need only ask" in order to determine whether the treatment was negligent. *Id.* at 122. The Court added that "it does not appear that [the plaintiff] ever made any inquiry," *id.* at 123, and that "[t]o excuse him from promptly doing so by postponing the accrual of his claim would undermine the purpose of the limitations

statute, which is to require the reasonably diligent presentation of tort claims against the Government," *ibid.*

Ultimately, the Court rejected not only a rule under which the limitations period would begin to run once "the plaintiff knew or could reasonably be expected to know of the Government's breach of duty," but also a more restrictive, inquiry-notice-style rule under which the period would begin to run once "the plaintiff had reason to suspect or was aware of facts that would have alerted a reasonable person to the possibility that a legal duty to him had been breached." *Kubrick*, 444 U.S. at 125. Just as information specifically relating to negligence is unnecessary for the limitations period for FTCA medical-malpractice claims to begin running, so too is information specifically relating to scienter unnecessary, when a securities-fraud plaintiff has notice of the "critical facts" underlying his claim, to put the plaintiff on inquiry notice.

In *Klehr* v. *A.O. Smith Corp.*, 521 U.S. 179 (1997), and *Rotella* v. *Wood*, 528 U.S. 549 (2000), the Court considered the limitations period for civil actions under the Racketeer Influenced and Corrupt Organizations Act (RICO). In *Klehr*, the Court rejected the position that the limitations period began to run only when the plaintiff knew, or should have known, of the last predicate act that was part of the pattern of racketeering activity. 521 U.S. at 186-191. The Court reasoned that such a rule "would permit plaintiffs who know of the defendant's pattern of [racketeering] activity simply to wait, sleeping on their rights, as the pattern continues and treble damages accumulate." *Id.* at 187 (internal quotation marks and citation omitted). And in *Rotella*, the Court rejected the position that the limitations period for civil RICO claims began to run only when the plaintiff discovered both the injury and the pattern of racketeering activity.

528 U.S. at 554. The Court reasoned that, while discovery of a pattern of racketeering activity may be complex, the same could have been said about the discovery of negligence in *Kubrick*, yet "its discovery is not required before the statute starts running." *Id.* at 556. Once again, just as a plaintiff need not know of certain elements of his claim for the limitations period for civil RICO claims to begin running, a plaintiff need not possess information specifically relating to scienter in order to be on inquiry notice of a Section 10(b) violation. Because the court of appeals' contrary rule cannot readily be reconciled with this Court's jurisprudence on the discovery rule, it should be rejected.

e. Notably, in an amicus brief in a companion case at the certiorari stage, the government made no effort to defend the bright-line rule that the court of appeals in this case adopted. Instead, the government contended that, in order to be on inquiry notice, a plaintiff need not possess information that the defendant acted with scienter when the alleged misstatement was "false for reasons likely to have been within the knowledge of the [defendant] when making it," but must possess such information when the alleged misstatement "concern[ed] information that is external to the [defendant]." U.S. Br. at 11-12, *Trainer Wortham & Co.* v. *Betz* (No. 07-1489) (internal quotation marks and citation omitted).

The government correctly recognized that there is no support for the court of appeals' bright-line rule, and the Court need only reject that rule in order to reverse the judgment below. In order to provide additional guidance to the lower courts, the Court may also wish to note that, when a plaintiff has reason to believe that a defendant has made a misstatement, the plaintiff ordinarily will be on inquiry notice, because he should at least suspect the

possibility that the defendant made the misstatement with scienter.

The government's formulation is seemingly consistent with that principle, because the mine run of alleged misstatements, as in this case, will presumably involve information that is "within the knowledge of" or "internal to" the defendant—and will therefore, under the government's formulation, put prospective plaintiffs on inquiry notice. But the government's formulation—which apparently originates from passing statements in a Seventh Circuit opinion, see *Law*, 113 F.3d at 785—may generate artificial and unnecessary complexities in operation, because it may not always be easy to determine whether a representation concerns information that is "internal" or "external" to the defendant (even if it is easy to do so in this case, see pp. 38-39, *infra*). And it is far from clear whether it would be appropriate to frame an inflexible rule under which a plaintiff can *never* be on inquiry notice absent information specifically relating to scienter when a statement concerns information that is "external" to the defendant. For those reasons, the Court need not embrace the government's alternative formulation here. Instead, the Court need only hold that the court of appeals erred by requiring the plaintiff to possess information specifically relating to scienter in order to be on inquiry notice.

3. To Trigger The Limitations Period In Section 1658(b), A Plaintiff Need Not Possess Sufficient Information To Survive A Motion To Dismiss

The implicit premise of the court of appeals' bright-line rule requiring information specifically relating to scienter for inquiry notice—and the explicit premise of the government's proposed rule requiring such information in at least some circumstances—is that, in order for discovery to occur for purposes of Section 1658(b), a

plaintiff must possess (or be deemed to possess) sufficient information to file a complaint that would survive a motion to dismiss. See U.S. Br. at 9, *Trainer Wortham*, *supra*. Whatever the exact meaning of Section 1658(b), see pp. 41-43, 46-47, *infra*, that premise is invalid.

a. To begin with, that premise simply cannot be reconciled with the language of Section 1658(b) itself. The limitations period in Section 1658(b) begins to run upon discovery of the "facts constituting the violation"—*i.e.*, the violation of Section 10(b)—and not upon discovery of all of the facts necessary to pursue a private cause of action. As this Court has recognized, the implied private cause of action under Section 10(b) contains certain additional elements beyond those required for a *violation* of that provision. See, *e.g.*, *Dura Pharm., Inc.* v. *Broudo*, 544 U.S. 336, 341-342 (2005) (listing elements). A plaintiff could therefore be on notice for purposes of Section 1658(b) even if he had not discovered information bearing on certain elements of his claim: for example, when the plaintiff had discovered information indicating that the defendant had made a misstatement, but had not yet determined that the misstatement had caused him to suffer a loss (and thus could not yet file a complaint). See 1934 Act § 21D(b)(4), 15 U.S.C. 78u-4(b)(4).

Significantly, the Securities and Exchange Commission (SEC) has taken the position that "[t]he date of a Rule 10b-5 'violation' need not coincide with the 'accrual' of a cause of action"; in a case involving an alleged misrepresentation, the SEC explained, "the 'violation' occur[s] when false statements [a]re made." SEC Br. at 21 n.30, *Lampf*, *supra* (No. 90-333). This Court appears to have accepted that understanding in *Lampf* itself, see 501 U.S. at 364 (concluding that the complaints at issue were untimely under the repose provision of Section 9(e) because they were filed "more than three years after pe-

titioner's alleged misrepresentations"), and even the Third Circuit has previously recognized that the term "violation" in Section 1658(b) refers to the defendant's misrepresentation, not to the accrual of a plaintiff's entire cause of action, see *In re Exxon Mobil Corp. Sec. Litig.*, 500 F.3d 189, 200 (2007).

A contrary rule would effectively require a court to engage in the difficult task of passing on the sufficiency of the allegations in the complaint before determining whether the complaint was untimely, because the natural starting point for the determination of whether a plaintiff could hypothetically have filed a complaint that would survive a motion to dismiss (thus triggering the limitations period) would be whether the plaintiff *did* in fact file a valid complaint. As a result, where a defendant wishes to raise both a limitations defense and a pleading defense, the defendant would be forced either to choose between the two defenses or to advance effectively inconsistent arguments. That rule cannot be the law, because it would "go far to eliminate the statute of limitations as a defense separate from" a pleading defense. *Kubrick*, 444 U.S. at 125. There is therefore no plausible basis for concluding that a plaintiff must be able to file a securities-fraud complaint before the limitations period can even start to run.

b. With regard to those elements that are required for a violation of Section 10(b), moreover, it is not necessary that the plaintiff possess sufficient information to satisfy any heightened pleading requirements applicable to those elements before the limitations period begins running. In the Private Securities Litigation Reform Act of 1995 (PSLRA)—enacted after this Court first set out the limitations period for Section 10(b) actions in *Lampf*—Congress adopted heightened pleading requirements for private securities-fraud actions, including

the requirement that the complaint "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 1934 Act § 21D(b)(2), 15 U.S.C. 78u-4(b)(2).

In *Rotella*, this Court considered and rejected the argument that the existence of heightened pleading requirements should drive application of the discovery rule. Specifically, the Court rejected the plaintiff's contention that it should adopt a broader version of the discovery rule for civil RICO claims on the ground that, in many cases, those claims were subject to the heightened pleading requirement for fraud claims in Federal Rule of Civil Procedure 9(b). 528 U.S. at 560-561. While acknowledging the plaintiff's concern that a narrower rule could "allow[] blameless ignorance to defeat a claim," the Court concluded that "we simply do not think such a concern should control the decision about the basic limitations rule." *Id.* at 560 (internal quotation marks and citation omitted). Although the PSLRA operates differently in some respects from Rule 9(b), the basic point remains the same: under the discovery rule, the limitations period may be triggered even when a plaintiff will not possess sufficient information to satisfy any applicable heightened pleading requirements.

It is therefore true, at least as a theoretical matter, that, under Section 1658(b), a plaintiff may not be in a position to file a securities-fraud complaint that would survive a motion to dismiss before the limitations period runs. Even when the discovery rule is applicable, however, the purpose of the limitations period *itself* is to give the plaintiff a specified period of time in which to "prepare a case against [the] perpetrators"—not to sit on his complaint once it is ready. *Lampf*, 501 U.S. at 378 (Kennedy, J., dissenting); see, *e.g.*, *Fujisawa Pharm. Co.* v. *Kapoor*, 115 F.3d 1332, 1334 (7th Cir. 1997). As the gov-

ernment has previously explained in another case involving the discovery rule, "statutes of limitations are designed to induce prospective plaintiffs to investigate and act; they are not designed to offer a period of leisure between the completion of an investigation and the filing of suit." U.S. Br. at 13, *Kubrick, supra* (No. 78-1014). The possibility that a heightened pleading requirement "will exact some cost," insofar as some plaintiffs may be unable to prepare valid complaints within the limitations period, is thus an insufficient basis for adopting a broader interpretation of the discovery rule. *Rotella*, 528 U.S. at 560.

c. Significantly, in extending the limitations period for Section 10(b) claims from one year to two years in the Sarbanes-Oxley Act, Congress acted out of concern that the preexisting one-year period would foreclose plaintiffs who were unable to prepare complaints sufficient to satisfy the PSLRA's heightened pleading requirements in time. In its report, the Senate Judiciary Committee observed that "[t]he one year statute of limitations from the date the fraud is discovered is * * * particularly harsh on innocent defrauded investors," because "the complexities of how the fraud was executed often take well over a year to unravel, even after the fraud is discovered." S. Rep. No. 146, *supra*, at 9. Specifically, the committee noted that, "[w]ith the higher pleading standards that * * * govern securities fraud victims, it is unfair to expect victims to be able to negotiate such obstacles in the span of 12 months." *Ibid.* That concern would have been wholly misplaced if the one-year period did not begin to run until the plaintiff possessed enough information to satisfy the PSLRA's heightened pleading requirements in the first place.

Conversely, if the limitations period were triggered only once a plaintiff was able to bring suit, the practical

effect of Congress's adoption of heightened pleading requirements in the PSLRA would have been to postpone the start of the limitations period, sometimes significantly, in many cases. Given that the PSLRA's primary purpose was to "check * * * abusive litigation by private parties," *Tellabs Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007), it is implausible that, in enacting the PSLRA, Congress would have wanted effectively to extend the time for filing private securities-fraud actions—and thus to enable more plaintiffs to use securities-fraud actions as a hedge against downside risk. See pp. 48-49, *infra*. In sum, the limitations period in Section 1658(b) is triggered by something short of the ability to file a viable complaint, and there is therefore no valid statutory basis for the court of appeals' rule that a plaintiff must possess information specifically relating to scienter in order to be on inquiry notice.

4. Under Any Standard, Respondents Were On Inquiry Notice Of Their Securities-Fraud Claim More Than Two Years Before The Initial Version Of The Complaint Was Filed

a. Should the Court agree that a plaintiff is not required to possess information specifically relating to scienter to be on inquiry notice, "it is clear," as the district court concluded in applying the correct legal standard, that respondents were on inquiry notice of their claim more than two years before the initial version of the complaint was filed. Pet. App. 97a.

As the district court explained at length, there was an "overwhelming collection of information * * * in the public realm" by no later than October 9, 2001, suggesting the possibility that petitioners had engaged in securities fraud in connection with their statements concerning

Vioxx. Pet. App. 85a.[6] Most importantly, FDA—the primary regulatory agency overseeing Merck's representations regarding Vioxx—had issued a warning letter charging Merck with "engag[ing] in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the [VIGOR] study, and thus, misrepresents the safety profile for Vioxx." J.A. 340. In addition, there was an enormous volume of news stories, academic articles, and analyst reports debating the merits of (and, in many instances, casting doubt on) Merck's position that the "likely" explanation for the disparity in cardiovascular events was that naproxen prevented blood clots. See, *e.g.*, J.A. 319-338, 355-507. And there were numerous pending lawsuits, particularly in the wake of the FDA warning letter, that specifically accused Merck of making misstatements concerning the cardiovascular risks associated with Vioxx. See J.A. 868-958. Overall, as the

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[6] The question whether respondents were on inquiry notice of their securities-fraud claim is conceptually distinct from the question whether respondents will ultimately prevail on the merits of that claim—and, for that reason, it is entirely consistent for petitioners to contend that respondents were on inquiry notice, on the one hand, but to maintain that Merck did not commit securities fraud, on the other. The former question focuses on what information was in respondents' possession, or in the public domain, that would have *suggested the possibility* that petitioners had engaged in securities fraud, regardless whether petitioners in fact did. And as to the latter question, Merck vigorously denies that it made misrepresentations concerning Vioxx's safety profile, and, in particular, has consistently expressed its strong disagreement with many of the allegations in the FDA warning letter. Notably, the SEC's Division of Enforcement recently informed Merck that it does not intend to recommend any enforcement action regarding Merck's statements concerning Vioxx. See Merck & Co., Inc., Quarterly Report (Form 10-Q), at 26 (Aug. 3, 2009).

district court noted, "the torrent of publicity" concerning Vioxx was "more akin to thunder, lightning and pouring rain than subtle warnings of a coming storm." Pet. App. 94a.[7]

To the extent that the court of appeals attempted to cast doubt on the relevance of the various sources of information on which the district court relied, its reasoning was patently flawed. With regard to the FDA warning letter, the court reasoned that "FDA was acting as a regulator of drug advertising, rather than as a regulator of the securities markets." Pet. App. 42a. That is true, but it does not follow that the widely publicized FDA warning letter—with its explicit accusation that Merck had "misrepresent[ed] the safety profile for Vioxx"—should be discounted for purposes of the inquiry-notice analysis simply because it was not issued by the SEC (and did not specifically accuse Merck of *securities* fraud). With regard to the filing of other lawsuits, the court of appeals similarly reasoned that "none of th[o]se lawsuits alleged securities fraud." *Id.* at 45a. That is also true, but it does not follow that the lawsuits—which accused Merck of making public misrepresentations concerning Vioxx's safety profile, and were therefore premised on the same underlying factual allegations—should be discounted simply because they did not assert the same cause of action. See, *e.g.*, *Masters* v. *GlaxoSmithKline*, 271 Fed. Appx. 46, 49 (2d Cir. 2008). Under the correct legal standard, respondents were plainly on in-

[7] As the information in question came into the public domain, it was reflected in Merck's stock price, which dropped substantially over the course of 2001 (and precipitously in the immediate aftermath of the FDA warning letter). See J.A. 826-832.

quiry notice of their claim more than two years before the initial complaint was filed.

b. In any event, respondents possessed not only information suggesting the possibility that petitioners made material misstatements, but also information specifically suggesting the possibility that they did so with scienter—and, for that reason, respondents were on inquiry notice more than two years before the initial complaint even under the court of appeals' standard.

As noted above, the FDA warning letter charged Merck with "minimiz[ing] the potentially serious cardiovascular findings that were observed in the [VIGOR] study, and thus, misrepresents the safety profile for Vioxx." J.A. 340. Those charges of deliberate wrongdoing—again, made publicly by the primary regulatory agency overseeing Merck's representations regarding Vioxx—would have sufficed to make a reasonable investor at least suspect the possibility that the alleged misstatements had been intentionally or recklessly made.[8]

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[8] At the certiorari stage, respondents suggested that this case should be analyzed differently because they had alleged not misstatements of fact, but rather misstatements of opinion or belief: *i.e.*, that Merck had expressed its *belief* that the likely explanation for the disparity in cardiovascular events was that naproxen prevented blood clots. See, *e.g.*, Br. in Opp. 29-31. Over the course of this litigation, respondents have taken seemingly inconsistent positions as to whether the alleged misstatements were statements of opinion, perhaps because misstatements of opinion are actionable only in limited circumstances. See, *e.g.*, Resp. D. Ct. Mem. of Law in Opp. to Mot. to Dis. 33 (filed Mar. 15, 2006). Assuming, however, that the alleged misstatements are better characterized as statements of opinion, the relevant inquiry under the court of appeals' standard would be whether the opinion at issue was "h[e]ld * * * in earnest." Pet. App. 33a. To the extent that FDA accused Merck of "misrepresent[ing] the safety profile for Vioxx," it would at a

Similarly, in the pending lawsuits, the plaintiffs alleged that Merck had, *inter alia*, "omitted, suppressed, or concealed material facts concerning the dangers and risks associated with Vioxx" and "*purposefully* downplayed and/or understated the serious nature of the risks associated with Vioxx." J.A. 893 (emphasis added). Those allegations, too, suggested the possibility that petitioners acted with scienter, and thus put respondents on inquiry notice even under the court of appeals' standard.

Notably, at least at earlier stages of the litigation, the plaintiffs in this case seem to have acknowledged as much—and thus to have pleaded themselves out of court. Prior versions of the complaint alleged that the FDA warning letter "put [petitioners] on notice * * * that [petitioners'] public statements concerning the safety of VIOXX were false and misleading." *E.g.*, J.A. 266 (Second Amended Complaint). Moreover, those versions of the complaint affirmatively cited both the FDA warning letter and the pending lawsuits as evidence of scienter, in a section of the complaint entitled "Additional Scienter Allegations." See, *e.g.*, J.A. 265, 266, 267. Although respondents conveniently omitted those allegations from the operative version of the complaint, they can hardly complain if the Court holds them to the earlier characterization of the warning letter and the pending lawsuits, and concludes, based on that characterization, that respondents possessed information specifically suggesting the possibility that petitioners acted with scienter as of the relevant date.[9]

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minimum suggest the possibility that any opinion expressed by Merck concerning Vioxx's safety profile was not sincerely held.

[9] Moreover, insofar as respondents contend that they were not on inquiry notice before November 6, 2001, because they did not pos-

c. Finally, respondents were also on inquiry notice more than two years before the initial complaint under the government's proposed standard, pursuant to which it is unnecessary for the plaintiff to possess any information specifically relating to scienter as long as the alleged misstatements involved information that is "within the knowledge of," or "internal to," the defendant. U.S. Br. at 11-12, *Trainer Wortham*, *supra*.

By respondents' own admission, "[t]he gravamen of [their] [c]omplaint was that [petitioners] made false statements of opinion by asserting that they believed that the results of the large-scale [VIGOR] clinical trial * * * were attributable to alleged cardioprotective properties of naproxen." Br. in Opp. 5. There can be no question but that Merck's alleged misstatements concerning the results of the VIGOR study involved information "within the knowledge of," or "internal to," Merck itself, because it was Merck that conducted the study. Indeed, the March 27, 2000, press release, on which respondents so heavily focus in their complaint, was issued even before the results of the study were publicly released. See J.A. 291-294. And the government's standard is even more clearly satisfied to the extent that the alleged misstatements are properly characterized, as respondents have suggested, as statements of Merck's own opinion or belief. See p. 36 n.8, *supra*. Under the

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sess any information specifically relating to scienter as of that date, they have failed to identify any such information that came into their possession *after* November 6, 2001, but before November 6, 2003—the date on which the first action asserting a securities-fraud claim was filed. See J.A. 265-269. The apparent implication of respondents' theory, therefore, is that respondents were not on inquiry notice even as of the date on which the initial version of the complaint was filed.

government's standard—or, for that matter, under any other standard—respondents were on inquiry notice more than two years before the initial complaint was filed.

B. Because Respondents Were On Inquiry Notice Of Their Securities-Fraud Claim More Than Two Years Before The Initial Complaint, Yet Failed To Conduct A Reasonably Diligent Investigation, Their Claim Was Untimely

The question presented in the petition for certiorari focused on whether the court of appeals erred by holding that a securities-fraud plaintiff is not on inquiry notice until he possesses information that the defendant acted with scienter. See Pet. i. The Court need only address that issue in order to dispose of this case. However, because there is a circuit conflict on the broader issue of how the date on which a plaintiff is on inquiry notice affects the running of the statute of limitations, see Pet. 20, the Court may wish to address that issue as well. If it does, it should hold that, at least where, as here, the plaintiff fails to conduct a reasonably diligent investigation after being placed on inquiry notice of a Section 10(b) violation, the limitations period begins to run from the date of inquiry notice.

1. a. The courts of appeals have taken conflicting positions as to when the limitations period begins running for a plaintiff who is on inquiry notice. Some courts have categorically held that the limitations period begins to run from the date of inquiry notice, however that date is defined. See Pet. 20-21 (citing cases). That approach is consistent with the manner in which the principle of inquiry notice has traditionally operated. As this Court has explained, "[w]hatever is notice enough to excite attention and put the party on his guard and call for inquiry, is notice of every thing to which such inquiry

might have led." *Wood*, 101 U.S. at 141 (quoting *Kennedy* v. *Green*, 3 Myl. & K. 699, 722, 40 Eng. Rep. 266, 275 (Ch. 1834) (opinion of Lord Brougham)). Accordingly, in numerous States, the limitations period for fraud claims runs from the date of inquiry notice (though the limitations period itself is sometimes subject to equitable tolling or estoppel). See, *e.g.*, *Jones* v. *Kassouf & Co., P.C.*, 949 So. 2d 136, 140 (Ala. 2006); *Holman* v. *Hansen*, 773 P.2d 1200, 1203 (Mont. 1989); *Association of Commonwealth Claimants* v. *Moylan*, 517 N.W.2d 94, 102 (Neb. 1994).[10]

Such a categorical approach—under which the date on which the plaintiff was on inquiry notice would always trigger the running of the limitations period—is also consistent with the manner in which statutes of limitations operate more generally. As discussed above, even when the applicable limitations period is subject to the discovery rule rather than the ordinary accrual rule, the purpose of the limitations period itself is to give the plaintiff time to complete the investigation of his claim. See pp. 31-32, *supra*. For that reason, no inequity would result from requiring the plaintiff to conduct the inquiry contemplated by the doctrine of inquiry notice during that period, and foreclosing the plaintiff from filing suit when he fails to complete that inquiry before the period runs. A categorical approach would also be relatively straightforward in its application, because there will of-

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[10] Some courts considering the limitations period for fraud claims have suggested that a plaintiff is not on inquiry notice *in the first place* if a reasonably diligent investigation would not have turned up the remaining information necessary to fill in any missing element. Such an approach would be roughly equivalent to the broader approach discussed below, and it should be rejected in this context for the same reasons. See pp. 48-51, *infra*.

ten be a particular event that unambiguously places a plaintiff on inquiry notice—and therefore, under that approach, triggers the limitations period. Cf. Pet. App. 86a (noting that, in this case, the FDA warning letter "arguably * * * alone [was] sufficient to put [respondents] on inquiry notice of their claims against Merck").

b. In its recent amicus brief, the government contended that, insofar as a plaintiff could be on inquiry notice without possessing information specifically relating to scienter, such a categorical approach would be inconsistent with the text of Section 1658(b). See U.S. Br. at 10, *Trainer Wortham*, *supra*. That contention lacks merit.

To begin with, the better view is that the phrase "facts constituting the violation" in Section 1658(b) does not encompass the fact of scienter in the first place. Although scienter is an element of a violation of Section 10(b), the phrase "facts constituting the violation" is properly understood to reach only the core nucleus of facts concerning the defendant's *conduct*, separate and apart from the fact of the defendant's *state of mind*. See generally 2 Corman § 11.5.7, at 202 (noting that, under the discovery rule, "[a]ccrual of the plaintiff's cause of action does not depend on his or her acquisition of information in proof of scienter").[11] Indeed, that appears to have been how this Court used a materially identical phrase in *Tellabs*, when it noted, in summarizing the PSLRA's heightened pleading requirements, that the PSLRA "require[d] plaintiffs to state with particularity

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[11] In at least one State in which the limitations period for fraud claims is triggered by discovery of the "facts constituting the fraud," that phrase has expressly been construed to exclude the fact of scienter. See *Stroh Die Casting*, 502 N.W.2d at 143 n.18.

both the facts constituting the alleged violation[] *and* the facts evidencing scienter." 551 U.S. at 313 (emphases added); cf. Fed. R. Civ. P. 9(b) (providing that "a party must state with particularity the circumstances constituting fraud" but that "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally"). Insofar as the phrase "facts constituting the violation" does not reach the fact of scienter, it would necessarily follow that a plaintiff could discover the relevant facts for purposes of Section 1658(b) without possessing information specifically relating to scienter.

Even if the phrase "facts constituting the violation" were construed to mean facts bearing on all of the elements of the violation, however, such a categorical approach would still not be irreconcilable with the text of Section 1658(b), as the government has suggested. To the contrary, under that approach, a plaintiff who is on inquiry notice could be deemed, as a constructive matter, to have "discover[ed] * * * the facts constituting the violation," even if he does not possess information specifically bearing on each and every element of the violation. When a plaintiff suspects a violation, the plaintiff would have imputed knowledge of the "facts constituting the violation"; the plaintiff would then have the duration of the limitations period to complete an investigation and obtain the remaining information necessary to fill in any missing element and file suit. See, *e.g.*, *Norgart* v. *Upjohn Co.*, 981 P.2d 79, 88 (Cal. 1999) (explaining that a plaintiff "discovers the cause of action when he at least suspects a factual basis * * * for its elements" and that, "within the applicable limitations period, he must indeed seek to learn the facts necessary to bring the cause of action in the first place"). A categorical approach is therefore consistent not only with a substantial body of case law on the doctrine of inquiry notice, but

also with the language of Section 1658(b). And petitioners would prevail under that approach, because respondents were on inquiry notice by no later than October 9, 2001—more than two years before the initial version of the complaint was filed. See pp. 33-39, *supra*.

2. At most, when a securities-fraud plaintiff is on inquiry notice of his claim, the plaintiff should be entitled to an additional period of time before the limitations period commences only when he conducts a reasonably diligent investigation. That is essentially the approach previously taken by the court of appeals below, and the approach long taken by the Second Circuit—the circuit with the most experience in considering securities-fraud claims. See Pet. 22 n.8 (citing cases).

a. An approach that gives the plaintiff the benefit of additional time only when he actually conducts an investigation follows naturally from this Court's jurisprudence concerning the discovery rule. As discussed above (see p. 16), the discovery rule originated in equity, and it therefore "inherent[ly]" incorporates the equitable principle that a plaintiff must exercise due diligence in discovering the violation—and that, when a plaintiff sleeps on his rights and "fail[s] to make inquiry," he is not entitled to the benefit of the rule. *United States* v. *Diamond Coal & Coke Co.*, 255 U.S. 323, 333 (1921). Accordingly, in its cases discussing the operation of the discovery rule, this Court has repeatedly emphasized the need for the plaintiff to have acted with reasonable diligence in prosecuting the investigation. See, *e.g.*, *Holmberg* v. *Armbrecht*, 327 U.S. 392, 396 (1946); *Wood*, 101 U.S. at 141, 143; *Bailey*, 88 U.S. (21 Wall.) at 348, 349-350.[12]

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[12] Lower courts, too, have long required plaintiffs to show that "their failure to make the discovery sooner was not due to their own

Under the approach of the Second and Third Circuits, once a plaintiff is on inquiry notice, the limitations period will begin to run unless the plaintiff conducts a further inquiry of his own.[13] That approach strikes a reasonable balance between defendants' interest in repose, on the one hand, and plaintiffs' interest in remediation, on the other. In particular, it creates appropriate incentives for plaintiffs to conduct a prompt investigation of potential claims at the point of inquiry notice.

This Court has recognized the need for similar incentives in the context of civil RICO claims, in which the Court has held that a plaintiff must act with reasonable diligence in order to invoke the doctrine of fraudulent concealment. See *Klehr*, 521 U.S. at 193-196. In so holding, the Court noted that "private civil [RICO] actions

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lack of diligence." *Del Campo* v. *Camarillo*, 98 P. 1049, 1054 (Cal. 1908); see, *e.g.*, *Teall* v. *Slaven*, 40 F. 774, 778 (C.C.D. Cal. 1889); *Andrews* v. *Dole*, 1 F. Cas. 878, 884 (D.N.J. 1875).

[13] To be sure, the Second Circuit has sometimes stated that the relevant question is whether the plaintiff conducted *any* inquiry—thus raising the possibility that the plaintiff who conducts any inquiry is entitled to the benefit of the additional time that it would have taken for a *reasonably diligent* plaintiff to obtain the necessary additional information. See, *e.g.*, *LC Capital Partners, LP* v. *Frontier Ins. Group, Inc.*, 318 F.3d 148, 154 (2d Cir. 2003). The question is more appropriately framed in terms of whether *the plaintiff* conducted a reasonably diligent inquiry. Indeed, in applying the Second Circuit's rule, some district courts appear to have interpreted it in precisely that fashion. See, *e.g.*, *Addeo* v. *Braver*, 956 F. Supp. 443, 449 (S.D.N.Y. 1997) (Sotomayor, J.). Those courts were correct to do so, because it would contravene the fundamental equitable principles underlying the discovery rule if a plaintiff who conducts a patently insufficient inquiry (*e.g.*, by simply watching the Today show every morning to see whether there have been any further developments concerning Vioxx) were entitled to the benefit of what a more diligent inquiry would have uncovered.

seek not only to compensate victims but also to encourage those victims themselves diligently to investigate and thereby to uncover unlawful activity." *Id.* at 195. That rationale applies with equal (if not greater) force here, because the implied private right of action under Section 10(b), like the express private right of action under RICO, is designed to "supplement Government efforts to deter and penalize the respectively prohibited practices"—"an object pursued the sooner the better." *Rotella*, 528 U.S. at 557, 558.[14]

Moreover, the Second and Third Circuits' approach would impose minimal burdens on plaintiffs, because the reality of modern securities-fraud litigation is that there is a sophisticated plaintiffs' bar with the ability to conduct even the most complex investigations—and, to the extent that it takes cases on a contingent-fee basis, with every incentive to do so. Indeed, before the district court, counsel for respondents candidly conceded as much, while at the same time admitting that neither respondents nor their counsel had conducted an investigation in this case. See J.A. 999 (statement of Melvyn Weiss, counsel for respondents) (noting that "I think you have to take judicial notice of the fact that the plaintiffs' bar in the securities area is not asleep at the switch"); p. 48, *infra*. When counsel for a plaintiff conducts a rea-

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[14] Even in cases in which private plaintiffs would be time-barred, the SEC ordinarily retains the authority to pursue enforcement actions —which, unlike private actions, are expressly authorized by the 1934 Act. See 1934 Act § 21(d), 15 U.S.C. 78u(d). There is no limitations period for SEC enforcement actions in which the SEC seeks only injunctive relief; a five-year limitations period, triggered by accrual, applies when the SEC seeks civil fines or penalties. See 28 U.S.C. 2462. Notably, in this case, the SEC has to date refused to take any enforcement action. See p. 34 n.6, *supra*.

sonably diligent investigation on the plaintiff's behalf, the plaintiff may be credited with the additional time that it took to conduct that investigation before the limitations period even begins to run.

b. In its recent amicus brief, the government contended that the Second and Third Circuit's approach, like a more categorical approach, would be inconsistent with the text of Section 1658(b). See U.S. Br. at 15, *Trainer Wortham*, *supra*. That contention lacks merit.

As a threshold matter, the Second Circuit's rule requiring a plaintiff to conduct an investigation in order to forestall the running of the limitations period was well established by the time Congress enacted Section 1658(b); indeed, in the legislative history, several Senators cited that rule with approval. See S. Rep. No. 146, *supra*, at 29 (additional views of eight Senators). Because Section 1658(b) was not intended to "chang[e] the basic standards of the law" with regard to the running of the limitations period, 148 Cong. Rec. 12,502 (2002) (statement of Sen. Leahy), there is no reason to believe that, by enacting Section 1658(b), Congress intended somehow to abrogate that rule.

More broadly, the Second and Third Circuits' approach readily comports with the language of Section 1658(b) itself. That approach could be understood to work in one of two functionally equivalent ways: (1) as extending the discovery period when a plaintiff conducts a reasonably diligent investigation, or (2) as starting the limitations period from the date of inquiry notice and providing for equitable tolling for the duration of a reasonably diligent investigation. As discussed above (see p. 43), the former understanding better comports with this Court's jurisprudence concerning the discovery rule, because the discovery rule itself "incorporates equitable considerations," including the principle that a plaintiff

must conduct a diligent inquiry in order to invoke the benefit of the rule. U.S. Br. at 28, *United States* v. *Beggerly*, 524 U.S. 38 (1998) (No. 97-731). Because the discovery rule already accommodates a plaintiff's diligence, there is no need to overlay a discrete doctrine of equitable tolling. Indeed, that appears to have been how this Court understood the limitations provision it adopted in *Lampf*, when it stated that the fact that the limitations period began running upon discovery of the facts constituting the violation "ma[de] tolling unnecessary." 501 U.S. at 363; see, *e.g.*, *TRW*, 534 U.S. at 30-31; *Beggerly*, 524 U.S. at 48.

Under the foregoing understanding of the Second and Third Circuits' approach, when a plaintiff conducts a reasonably diligent investigation and obtains the additional information necessary to fill in any missing element, he can be said at that point to have "discover[ed] * * * the facts constituting the violation." Conversely, when a plaintiff fails to conduct a reasonably diligent investigation, he can be deemed, as an equitable matter, to have "discovered" the relevant facts as of the date of inquiry notice. That approach therefore comfortably comports both with the language of Section 1658(b) and with the background understanding of the discovery rule. Should the Court reach the broader issue of how the date on which a plaintiff is on inquiry notice affects the running of the statute of limitations, it should at a minimum adopt that approach here.[15]

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[15] Insofar as the Court conceives of the Second and Third Circuits' approach as starting the limitations period from the date of inquiry notice and providing for equitable tolling for the duration of a reasonably diligent investigation, see, *e.g.*, *Rotella*, 528 U.S. at 561 (suggesting that equitable tolling could be available even when the the discovery rule is applicable), that approach can still be readily

Under the Second and Third Circuits' approach, just as under a more categorical approach, petitioners would prevail in this case. Notwithstanding the Third Circuit's prior adoption of that approach, respondents have never argued, in response to petitioners' limitations defense, that they undertook *any* investigation, much less a reasonably diligent investigation, in the wake of the events that placed them on inquiry notice. See, *e.g.*, Pet. App. 58a, 98a; cf. J.A. 994 (statement of Melvyn Weiss) (conceding, in response to the district court's question as to whether "you" or "your client" conducted an investigation, that "we didn't do it ourselves").

3. Some courts of appeals have held that, when a securities-fraud plaintiff is on inquiry notice of his claim, the plaintiff should be entitled to the additional period of time that it would take to complete a reasonably diligent investigation, regardless whether he actually conducted an investigation himself. See, *e.g.*, *Trainer Wortham*, 519 F.3d at 876. That approach should be rejected for three principal reasons.

a. Most fundamentally, when compared to the Second and Third Circuits' approach, the broader approach would effectively excuse a plaintiff's failure to conduct a further investigation after being placed on inquiry notice of a Section 10(b) violation, in contravention of basic equitable principles. Such an "ostrich" plaintiff would be in the same position as a plaintiff who does conduct a reasonably diligent investigation, because the limitations period would run from the same date: *i.e.*, from the con-

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reconciled with the language of Section 1658(b), because a plaintiff can constructively be deemed to have "discover[ed] * * * the facts constituting the violation" once he is on inquiry notice. See pp. 42-43, *supra*.

clusion of the reasonably diligent investigation (or, in the case of the "ostrich" plaintiff, a hypothetical reasonably diligent investigation). See *Fujisawa*, 115 F.3d at 1337. In a case involving a publicly traded company, the broader approach, when compared to the Second and Third Circuit's approach, would give the "ostrich" plaintiff more time to wait and "see how the price of his stock behave[s] in the interim," *ibid.*—and, if the price of the stock drops, to use a securities-fraud claim as a "partial downside insurance policy," *Dura*, 544 U.S. at 348. The broader approach would therefore "magnif[y]" "the opportunistic use of federal securities law to protect investors against market risk." *Tregenza* v. *Great Am. Commc'ns Co.*, 12 F.3d 717, 722 (7th Cir. 1993), cert. denied, 511 U.S. 1085 (1994).

Indeed, this case is a prime example of that phenomenon. Notwithstanding the information that was in the public domain as of October 9, 2001, the initial version of the complaint was not filed until November 6, 2003—by which time *more than two hundred* Vioxx-related lawsuits asserting other types of claims had already been filed. That filing date, moreover, was hardly coincidental. The initial complaint was filed shortly after Merck reported that its earnings would be lower than expected, in part because of falling sales of Vioxx due to widespread concerns about possible cardiovascular risks. See Pet. App. 18a. Unsurprisingly, that report caused Merck's stock price to drop considerably. See J.A. 848-849. The delay in bringing suit therefore allowed the plaintiffs to claim a bigger decline in Merck's stock price, and also enabled them to expand the size of their putative class—and thus exponentially multiplied the potential total value of the claims to the plaintiffs (and also, presumably, to their lawyers). See J.A. 999 (statement of Melvyn Weiss) (noting that "the earnings had materi-

ally dropped and that's what * * * securities lawyers look at").[16] A liberal approach to the running of the limitations period would facilitate the Topsy-like growth of plaintiffs' claims in cases such as this one, and thereby greatly increase the settlement value of those claims—and thus intensify the familiar pressures on defendants to settle securities-fraud claims regardless of their merit. See *Stoneridge*, 128 S. Ct. at 772.

b. In addition, the broader approach would lead to potentially grave difficulties in application, because it would force courts to engage in entirely hypothetical inquiries about what a reasonably diligent investigation would have entailed and how long it would have taken for such an investigation to bear fruit. By contrast, an approach that turned on the investigation the plaintiff actually conducted would require a court only to make the more focused determination whether *the particular plaintiff* acted with due diligence—a familiar task for courts in various areas of the law. See, *e.g.*, *District Att'y's Office for the Third Judicial Dist.* v. *Osborne*, 129 S. Ct. 2308, 2317 (2009) (noting that, under an applicable statutory provision, a convict could raise a claim based on newly discovered evidence only if it was "pursued with due diligence"). And an approach that turned entirely on the date of inquiry notice would be easier still to administer. See pp. 40-41, *supra*.

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[16] Indeed, in the operative version of the complaint—filed more than eighteen months later—respondents expanded their claims still further: specifically, by suggesting that they were entitled to recovery for the sizable additional stock-price drop that occurred after Vioxx was withdrawn from the market in 2004, and extending the class to include even persons who purchased Merck stock after Vioxx's withdrawal. See J.A. 24-28.

c. Finally, the broader approach would seemingly render the principle of inquiry notice irrelevant. Under that approach, it would be unnecessary for a court to engage in the threshold inquiry as to when the plaintiff was on inquiry notice, because the ultimate inquiry would be when a hypothetical plaintiff should have obtained sufficient information fully to "discover" the violation—regardless whether the plaintiff had earlier possessed information that should have led him to suspect the possibility of a violation in the first place.

There is no valid justification for effectively abrogating the principle of inquiry notice in that manner. As discussed above (see p. 20), the inquiry-notice principle is deeply rooted in the application of the discovery rule to fraud claims, has been accepted by all of the courts of appeals to have addressed the issue, and was ratified by Congress when it enacted Section 1658(b). An approach that takes the date of inquiry notice at least as the starting point sets an appropriate balance for private securities-fraud plaintiffs, so that they are not penalized for their lack of knowledge of a violation, on the one hand, but not rewarded for their failure to investigate a suspected violation, on the other. Should the Court reach the broader issue concerning the running of the statute of limitations, therefore, it should reject any more forgiving, and potentially open-ended, alternative approach.

* * * * *

At the end of the analysis, it bears remembering that this case involves an implied right of action for which Congress has never explicitly provided, even as it established a statute of limitations to govern claims brought by private parties. That fact counsels restraint in the interpretation of both substantive and procedural requirements governing private securities-fraud actions.

See, *e.g.*, *Stoneridge*, 128 S. Ct. at 773. If Congress wishes to liberalize any aspect of the statute of limitations for private securities-fraud claims, it can readily do so—as, indeed, it recently did by extending the limitations period from one year to two. For its part, however, this Court should exercise caution and leave "[t]he decision to extend the cause of action * * * for Congress." *Ibid.* The court of appeals' interpretation of the statute of limitations for private securities-fraud actions is unduly expansive and wrong. That interpretation should be rejected, and the judgment below reversed.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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RESPONDENT'S BRIEF

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IN THE
Supreme Court of the United States

MERCK & CO., INC., ET AL.,
Petitioners,

v.

RICHARD REYNOLDS, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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QUESTIONS PRESENTED

Under 28 U.S.C. §1658(b)(1), a limitations period of two years for a private securities-fraud action commences with "the discovery of the facts constituting the violation." The questions presented are:

1. Whether a reasonable Merck investor should have discovered petitioners' statements were material misrepresentations of belief and opinion as charged in respondents' complaint earlier than November 6, 2001.

2. Whether scienter is among the "facts constituting [a] violation" within the meaning of §1658(b)(1); and, if so, whether a reasonable Merck investor should have discovered petitioners' fraudulent intent earlier than November 6, 2001.

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INTRODUCTION

In the late 1990s, Merck perceived an anticipated new "blockbuster" drug, Vioxx, to be critical to its future financial prospects. The company's non-public internal data, however, indicated that Vioxx might cause serious cardiovascular risks. Recognizing Vioxx's importance, Merck executives embarked on a scheme to obscure those likely risks.

In 1999, after Merck's rival Pfizer had started a large clinical trial involving the competing drug Celebrex, Merck began a similar large-scale study, Vioxx Gastrointestinal Outcome Research ("VIGOR"). VIGOR's results indicated that Vioxx users had a significantly higher incidence of adverse cardiovascular events than users of naproxen. Because those results threatened Vioxx's commercial viability, Merck concocted a theory to explain them: VIGOR's results stemmed from cardio-*protective* qualities of naproxen, rather than any cardio-*damaging* attributes of Vioxx. Merck's theory, which it consistently promoted to the financial and medical communities, became known as the "naproxen hypothesis."

Merck's gambit succeeded. Based on Merck's public assurances that data from its other, non-public clinical trials "showed no indication" (JA293) that Vioxx users experienced more adverse cardiovascular events than patients taking placebo or comparator drugs other than naproxen, the financial and medical communities generally accepted the naproxen hypothesis as the most likely explanation of VIGOR's results. Although the market knew the hypothesis was unproven, no one questioned the sincerity of Merck's belief in it or whether Merck had a reasonable basis to advance it. Vioxx sales continued to grow, totaling more than $8 billion during 2001-

2004, and Merck's stock price remained artificially high.

On September 30, 2004, Merck suddenly and unexpectedly withdrew Vioxx from the market. In response, Merck's stock price dropped precipitously. Four weeks later, *The Wall Street Journal* ("*WSJ*") published leaked internal Merck emails written years before revealing Merck's longstanding belief that Vioxx caused adverse cardiovascular events.

Respondents allege that petitioners[1] repeatedly and falsely stated that Merck believed in the naproxen hypothesis and that those false representations of belief caused the market to conclude that Merck's revenue stream from Vioxx would remain secure. After convincing *doctors* to write billions of dollars of prescriptions up until Vioxx was suddenly withdrawn from the market in 2004, Merck now argues that its own *investors* were on notice of its fraud before November 2001. To support its counterintuitive theory, Merck asks the Court to interpret the two-year discovery prong of 28 U.S.C. §1658 as running from the first information "sufficiently suggestive of wrongdoing." Br. 20. Merck claims that it is legally irrelevant what kind of wrongdoing is suggested or whether the available information could lead to facts showing a violation of §10(b) of the Securities Exchange Act of 1934.

Merck's position cannot be reconciled with §1658's express command that the two-year limitations period does not begin to run until there has been "discovery of the facts constituting the violation" of §10(b). This Court should reject Merck's unsupportable reading of §1658 as inconsistent with text,

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[1] Petitioners hereafter are referred to collectively as "Merck."

precedent, and the purposes of the federal securities laws. The Court can also readily affirm the Third Circuit on the narrow ground on which it decided this case: two years before filing this action, respondents had no basis for even suspecting that Merck had materially misrepresented its opinion.

STATEMENT

A. Statutory And Doctrinal Background

In response to reports of widespread abuses in the securities industry, Congress enacted the Securities Act of 1933 ("1933 Act") and the Securities Exchange Act of 1934 ("1934 Act"). To advance their objective of "honest markets," *Basic Inc. v. Levinson*, 485 U.S. 224, 230 (1988) (internal quotations omitted), 1934 Act §10(b) forbids the use of "any manipulative or deceptive device or contrivance" "in connection with the purchase or sale of a security." 15 U.S.C. §78j(b).

In *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991), this Court drew from the "contemporaneously enacted express remedial provisions" of the 1933 and 1934 Acts to impose a statute of limitations for the implied right of action it had earlier recognized under §10(b). Finding the language of 1934 Act §9 (prohibiting manipulation of security prices) most appropriate, *Lampf* held that "[l]itigation instituted pursuant to §10(b) and [Securities and Exchange Commission ("SEC")] Rule 10b-5 . . . must be commenced within one year after the discovery of the facts constituting the violation and within three years after such violation." *Id.* at 364.

In 2002, in response to corporate frauds including Enron and Worldcom, Congress amended 28 U.S.C. §1658(b) to extend the limitations period for §10(b) claims, but preserved the language from §9. As a Senate sponsor stated: "[W]e are not suggesting

changing the basic standards of the law on a statute of limitation. . . . We are perfectly willing to have exactly the same words as the law says now, with the exception the statute is slightly longer." 148 Cong. Rec. 12,502 (2002) (statement of Sen. Leahy). In relevant part, §1658(b) provides:

> [A] private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws, as defined in section 3(a)(47) of the [1934 Act] (15 U.S.C. 78c(a)(47)), may be brought not later than the earlier of –
>
> (1) 2 years after the discovery of the facts constituting the violation; or
>
> (2) 5 years after such violation.

B. Nature Of The Action

1. Information that was publicly available

Merck is a multibillion dollar global pharmaceutical company. In the late 1990s, patents on five of its best-selling drugs were nearing expiration. JA51 (¶76).[2] Merck's best prospect for replacing the revenue it expected to lose was Vioxx, a new type of nonsteroidal anti-inflammatory drug ("NSAID") known as a Cox-2 inhibitor. Vioxx promised to provide the same pain relief as traditional NSAIDs (*e.g.*, aspirin, ibuprofen, and naproxen) with significantly reduced

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[2] The Fourth Amended Complaint was the operative complaint in the Third Circuit. JA20-263. After additional details of Merck's fraud emerged and the case was remanded, respondents filed, with Merck's consent, a Fifth Amended Complaint on March 10, 2009. The Fifth Amended Complaint is excerpted at JA270-90; the full version is available on PACER.

gastrointestinal side effects. Market watchers viewed Vioxx as critical to Merck's future. JA52 (¶77).

Vioxx received Food and Drug Administration ("FDA") approval in May 1999. JA60 (¶94). Nothing in the Precautions, Warnings, or Contraindications sections of Vioxx's product label suggested that it posed cardiovascular risks. Vioxx quickly met expectations, generating more than $2 billion in sales in its first year.

On March 27, 2000, Merck announced the preliminary results from VIGOR. Merck's press release reported that Vioxx users suffered significantly fewer gastrointestinal problems than naproxen users, but significantly more thromboembolic (*i.e.*, resulting from blood vessel blockage from clotting) events. The press release described these cardiovascular results as "consistent with Naproxen's ability to block platelet aggregation," adding: "VIOXX, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effect." JA83 (¶143). Merck's press release stated both that this benign explanation for VIGOR's results was not based on "any clinical studies of naproxen" and that "[a]n extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with Vioxx, showed no indication of a difference in the incidence of thromboembolic events between Vioxx, placebo and comparator NSAIDs." JA291, 293.

The financial and medical communities immediately understood that the naproxen hypothesis was unproven and that another possible explanation for VIGOR's results was that Vioxx increased the risk of heart attacks. *See, e.g.*, JA547 (JP Morgan: "it is impossible to determine if Vioxx patients had an in-

creased risk of suffering heart attacks, or if naproxen patients had a decreased risk"). Most, however, accepted the hypothesis as the best explanation for VIGOR's results, and no one questioned that Merck genuinely believed the hypothesis or had a reasonable basis for it. JA84, 94 (¶¶145, 163). Thereafter, Merck continued promoting the naproxen hypothesis as the "likely" explanation for VIGOR's increased incidence of cardiac events among Vioxx users (Br. 4) and repeatedly claimed it had non-public internal data showing "no difference in the incidence of cardiovascular events . . . among patients taking Vioxx, other NSAIDs and placebo." JA96 (¶166).

On February 8, 2001, a senior Merck scientist reiterated Merck's belief in the naproxen hypothesis at public FDA Arthritis Advisory Committee ("AAC") hearings on Merck's request for a revised drug label providing that Vioxx caused fewer gastrointestinal problems than traditional NSAIDs. 5thAC[3] ¶276. The AAC Chairperson, while noting the naproxen hypothesis remained unproven, stated that "[d]ifferences in cardiac risk between Vioxx and naproxen appeared to result from a beneficial effect of naproxen, not a danger from Vioxx." JA403; *see also* JA394. Contemporaneous news articles reported those statements. JA394, 403.

In August 2001, the *Journal of the American Medical Association* ("*JAMA*") published an article discussing possible cardiovascular risks associated with Cox-2 inhibitors, including Vioxx. JA319-38. It stated that, "[given] the evidence for an antiplatelet effect of naproxen, it is difficult to assess whether the difference in cardiovascular event rates in VIGOR

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[3] Corrected Consol. Fifth Am. Class Action Compl. (filed Mar. 10, 2009) ("5thAC").

was due to a benefit from naproxen or to a prothrombotic effect from [Vioxx]," JA327, and that a clinical trial should be conducted to assess possible cardiovascular risks of Cox-2 inhibitors, JA331. Just before it was published, Merck publicly stated: "We already have additional data beyond what [*JAMA*] cite[s], and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo." JA119 (¶214).

On September 21, 2001, FDA's website posted a warning letter that the agency's Division of Drug Marketing, Advertising, and Communications ("DDMAC") had sent to Merck four days earlier regarding certain Vioxx marketing activities. JA339-54. The letter primarily concerned statements made by a Merck consultant during teleconferences with doctors' groups in June 2001 and by Merck sales representatives at exhibit booths at two June 2001 pharmacist conventions. It stated that those promotional activities violated FDA-specific statutes and regulations that characterize as "false, lacking in fair balance, or otherwise misleading" any drug company promotional material that fails to disclose all of a drug's potential risks – even if those risks are already common knowledge. JA339 (citing 21 U.S.C. §§331, 352); *see* 21 C.F.R. §202.1(e)(5)(ii).

DDMAC's letter acknowledged that the naproxen hypothesis provided a "reasonable" explanation of VIGOR's results, but criticized those specific Merck promotions because they "fail[ed] to disclose that [the naproxen hypothesis] is hypothetical." JA340. DDMAC directed Merck to send a letter to the approximately 100 doctors and 1,300 pharmacists who attended the events at issue to confirm that the naproxen hypothesis remained unproven and that another possi-

ble explanation for VIGOR was that Vioxx raised the risk of cardiovascular events. JA353.

Following initial reports about DDMAC's letter, Merck's stock price declined by approximately $3 over two trading days – a brief dip one analyst attributed to market "[n]oise." JA626.[4] By September 25, 2001, leading financial analysts reported that DDMAC's letter contained no new information. A Dain Rauscher analyst wrote that the omissions flagged by DDMAC "likely" are "already common knowledge in the medical community." JA618. A Lehman report added: "Warning letters of this nature are certainly not unusual and in fact [are] almost a staple of the pharmaceutical industry today" – and characterized DDMAC as merely charging Merck with violating technical FDA drug marketing rules. JA624.

No analyst downgraded Merck's stock; most retained "buy" or "strong buy" ratings on Merck and maintained price targets well above Merck's then-current stock price. JA809-11. By September 27, 2001, four trading days after DDMAC's letter became public, Merck's stock price closed higher ($62.66) than it did on the date the letter was posted ($62.18); it continued to track the S&P's pharmaceutical index for months thereafter. JA832.

Between May 29, 2001, and October 1, 2001, four personal-injury complaints were filed alleging – based solely on VIGOR's results, *JAMA*'s article, and

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[4] "Noise" in this context is commonly defined as trading (typically by less sophisticated investors) done in the absence of meaningful new information. *See, e.g.*, Thomas Lee Hazen, *The Short-Term/Long-Term Dichotomy and Investment Theory: Implications for Securities Market Regulation and for Corporate Law*, 70 N.C. L. Rev. 137, 157 (1991).

DDMAC's letter – that Merck had failed directly to warn Vioxx users on an individual basis of the drug's potential risks. JA868-958. In SEC filings, Merck repeatedly stated that those suits were "completely without merit," JA126 (¶227), and were "considered normal to its business."[5]

On October 9, 2001, *The New York Times* ("*NYT*") published an article quoting petitioner Edward Scolnick, Merck's Chief Scientific Officer. Addressing possible explanations for VIGOR's results, Scolnick reiterated that "the likeliest interpretation of the data is that naproxen lowered the thromboembolic event rate" and said Merck had "found no evidence that Vioxx increased the risk of heart attacks." 5thAC ¶159.

In April 2002, FDA approved (1) Merck's proposed product label regarding Vioxx's gastrointestinal safety, and (2) expanded Vioxx's approved indications to include treatment for rheumatoid arthritis. JA145 (¶256). The new label also, for the first time, addressed Vioxx's cardiovascular safety profile in the "Precautions" section, stating that the "significance of the cardiovascular findings" from three studies (including VIGOR) "is unknown." JA140 (¶251). One week later, a Merck spokesperson repeated to analysts Merck's "belief that the effect seen in VIGOR were the results of the anti-platelet effect of naproxen." JA148 (¶258). Investors continued to purchase Merck stock – including many in the class who had not owned Merck shares prior to November 2001.

On October 30, 2003, the *WSJ* reported the results of a large-scale, observational study of 50,000

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[5] *See, e.g.*, Merck & Co., Form 10-Q, at 14 (filed Nov. 13, 2002).

Medicare patients performed by Harvard University's Brigham and Women's Hospital ("the Harvard Study"). The study, funded by an unrestricted Merck grant, found that Vioxx users had a significantly greater risk of heart attack than Celebrex users and an elevated risk compared to users who took other NSAIDs or no painkillers. JA164 (¶290). Merck immediately criticized the study's methodology and conclusions, and it reiterated its own purportedly reliable clinical trial data as finding "no significant difference" between Vioxx and placebo. JA165-66 (¶¶291, 293).

A week later, on November 6, 2003, an investor filed the first securities-fraud complaint against Merck. Meanwhile, Vioxx continued to generate billions in revenues for Merck – more than $2.5 billion annually in 2002 and 2003. JA55 (¶85).

On September 30, 2004, Merck abruptly withdrew Vioxx from the market after an independent safety monitoring board stopped a Vioxx trial due to "increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy." JA182 (¶321). Merck's shares fell almost 27% on that news – their greatest one-day percentage price decline in over a decade. JA856.

2. Non-public information subsequently disclosed

On November 1, 2004, a *WSJ* article disclosed previously secret internal Merck emails demonstrating that Merck had long harbored serious concerns that Vioxx was prothrombotic and viewed VIGOR's results as confirming those fears. JA189-97 (¶¶332-334). Merck shares plummeted another 10%. As one analyst reported: "the situation might not be as innocent as we thought." JA198 (¶337).

Additional details of Merck's fraud have since emerged. Those previously undisclosed facts –

brought to light through investigative newspaper articles, congressional hearings, and unsealed documents discovered in product liability lawsuits – further revealed how Merck (a) had long feared that Vioxx caused cardiovascular problems; (b) intentionally manipulated its reported research to mask Vioxx's harmful effects; and (c) fraudulently schemed to promote the naproxen hypothesis to avoid jeopardizing Vioxx's lucrative revenue stream.

Indeed, three years before Vioxx received FDA approval, Merck learned of data suggesting that Vioxx might lead to increased blood clotting and raise the risk of thrombotic events, as well as other non-public information indicating potential prothrombotic attributes of Vioxx. 5thAC ¶¶98-103, 111-113. Merck had planned to begin a large-scale clinical trial soon comparing Vioxx to naproxen. However, as one Merck scientist wrote, if Merck proceeded with the proposed trial, Vioxx users would suffer "more thrombotic events," which would "kill the drug." *Id.* ¶105. Another top Merck scientist, petitioner Alise Reicin, added: "the possibility of increased CV [cardiovascular] events is of great concern." *Id.* ¶107. Reicin instead proposed that Merck exclude from the trial patients at high risk of suffering cardiovascular problems, stating: "This may decrease the CV event rate so that a difference between the [Vioxx and naproxen] groups would not be evident." *Id.* ¶108. Instead, Merck cancelled the trial.

In February 1998, an internal Merck analysis showed that women taking Vioxx had a statistically significant 216% greater risk of adverse cardiovascular events, while men had a 28% increased risk. Merck concealed those adverse data, took steps to avoid developing further evidence that Vioxx might

cause cardiovascular problems, and continued pushing for FDA approval. *Id.* ¶¶117-122.

By early 1999, Pfizer had begun a large-scale trial to establish that Celebrex caused fewer serious gastrointestinal problems than traditional NSAIDs. The competitive threat from Celebrex forced Merck to proceed with VIGOR (the large-scale trial it cancelled years earlier). *Id.* ¶¶125-126.

In an attempt to mask any prothrombotic properties of Vioxx, Merck excluded from VIGOR patients at higher risk of suffering adverse cardiovascular events – exactly as petitioner Reicin had suggested years earlier. *Id.* ¶127. Nevertheless, Vioxx users still suffered significantly more adverse cardiovascular events than naproxen users. Internal emails show how those results confirmed to Merck – as petitioner Scolnick stated in one such email – that the cardiovascular events among Vioxx users "***are clearly there***" and that "***it is mechanism based as we worried it was***." *Id.* ¶¶137-138.

Before publicly announcing VIGOR's results, Merck scrambled to devise a plausible alternative explanation for its cardiovascular data. Despite their true beliefs and possession of significant contrary non-public information, *id.* ¶142, Merck concocted, then widely promoted, the naproxen hypothesis and continued to cover up subsequently developed adverse information, *id.* ¶¶160-193.

According to its August 3, 2009 Form 10-Q, Merck remains under criminal investigation by various governmental authorities in connection with Vioxx.

C. District Court Proceedings

On November 6, 2003, the initial securities-fraud action was filed, with later complaints consolidated

in the District of New Jersey. The Fourth Amended Complaint was filed in June 2005, which substantially elaborated on these earlier complaints. Merck moved to dismiss.

The district court dismissed respondents' §10(b) claims as time-barred, holding that respondents were on inquiry notice more than two years before the first action was filed. The court interpreted respondents' complaint to allege that Merck's fraud involved concealing that the naproxen hypothesis was unproven and that another possible explanation for VIGOR's results was that Vioxx caused adverse cardiovascular events. The court held that respondents were on "inquiry notice" of those facts no later than the October 9, 2001 *NYT* article, when Scolnick acknowledged that one explanation for VIGOR's results was that Vioxx might cause heart attacks; it also relied on DDMAC's September 2001 letter. Pet. App. 85a-86a.

Finding that "inquiry notice" existed as of October 9, 2001, the district court held that the limitations period ran from that date. *Id.* at 94a, 97a-98a.

D. The Third Circuit's Decision

The Third Circuit reversed, finding that the district court had mischaracterized respondents' claims and that "inquiry notice" occurred not earlier than October 30, 2003, when the *WSJ* reported the Harvard Study.

The Third Circuit found that respondents had *not* alleged that Merck misrepresented whether Vioxx might cause heart attacks, Pet. App. 33a-35a, noting that the possibility had been obvious from Merck's first announcement of VIGOR's results, *id.* at 39a-40a. The court read the complaint to allege that Merck misrepresented its *belief* in the naproxen hypothesis – *i.e.*, that Merck "did not hold th[e] opinions

or beliefs in earnest." *Id.* at 33a (citing *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1095 (1991)). It then found that, as of November 6, 2001, a reasonable investor would have had no reason to suspect that Merck's endorsement of the naproxen hypothesis falsely represented its opinion. *Id.* at 46a ("As of that date, market analysts, scientists, the press, and even the FDA agreed that the naproxen hypothesis was plausible, at the very least. None suggested that Merck believed otherwise.").

The Third Circuit concluded that the public documents on which the district court relied showed only that the hypothesis was unproven – a fact "Merck had long acknowledged and . . . the market had incorporated." *Id.* at 43a. The court concluded that neither DDMAC's letter nor the October 9, 2001 *NYT* article provided investors with new information or "charge[d] that the naproxen hypothesis was wrong or that Merck did not believe in the validity of its hypothesis." *Id.* Accordingly, those documents provided no "storm warnings" that Merck falsely represented its opinion on the proper interpretation of VIGOR's results. *Id.*

The Third Circuit observed: "[W]e must not lose focus of the nature of the allegations in [DDMAC's] letter and the scope of the FDA's regulatory authority. . . . [T]he FDA's drug advertising regulations and the securities laws provide wholly different standards with respect to what constitutes a misrepresentation." *Id.* at 41a-42a. The court concluded:

> [T]he fact that the FDA sent a letter to Merck about its possible misrepresentations in connection with its promotion of Vioxx to health care professionals would not have provided a storm warning unless it put [respondents] on

> inquiry notice of actionable misrepresentations under the securities laws. The asserted basis of [respondents'] claims is that Merck defrauded investors by proposing and reasserting the naproxen hypothesis at the same time that it knew the hypothesis was false.

Id. at 34a-35a (citation omitted). The court also found the handful of pre-November 2001 consumer lawsuits irrelevant because they did nothing more than "allege[] that Merck failed to provide publicly available information to Vioxx consumers." *Id.* at 45a.

The Third Circuit noted that Merck's stock price remained relatively unchanged through those 2001 developments and determined that the absence of any "significant [price] movement," though not conclusive, indicated that financial markets did not view DDMAC's letter or the October 2001 *NYT* article as providing significant new information. *Id.* at 44a-45a. The court also noted that analysts "continued to maintain their ratings for Merck stock and/or projected increased future revenues" after the purported storm warnings. *Id.* at 45a.

Accordingly, the court concluded that respondents timely filed suit. Judge Roth dissented.

SUMMARY OF ARGUMENT

I. The two-year limitations period for "a private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws," 28 U.S.C. §1658(b), begins upon "the discovery of the facts constituting the violation," *id.* §1658(b)(1).

A. The "facts constituting" a 1934 Act §10(b) violation are those that establish each of the elements of that violation: falsity, materiality, and scienter. In a case alleging misrepresentation of belief, as here, a misrepresentation must be "a misstatement of the psychological fact of the speaker's belief in what he says" and must "also mislead about the stated subject matter" because of something "false or misleading in what the statement expressly or impliedly declare[s] about its subject." *Virginia Bankshares*, 501 U.S. at 1095-96.

B. Although §1658(b)'s unqualified reference to "discovery" would in ordinary usage mean actual discovery, that term can also include constructive discovery. Under established precedent, constructive discovery of a fraud occurs when a reasonable investor would have discovered sufficient facts that, if proved, would establish falsity, materiality, and scienter. Constructive discovery does not include facts that would not or could not have been discovered through reasonable diligence.

C. "Inquiry notice" is merely a part of the constructive-discovery analysis. An investor is said to be on "inquiry notice" of fraud if, based on a retrospective analysis of what inquiries a reasonable investor would have made, and what that investor would have learned as a result, it is determined that

such investor would have discovered the facts constituting the violation.

Inquiry notice cannot be established merely by showing an investor had information to put him on his guard; the investor must also have "the means of discover[ing]" the fraud "in his power." *Wood v. Carpenter*, 101 U.S. 135, 141 (1879). Plaintiffs are not chargeable with constructive knowledge of information that defendants keep hidden.

D. The context and structure of §1658(b)(1) confirm this reading. The two-year limitations period is juxtaposed with a five-year repose period that protects defendants from indefinite exposure by running from the date of a §10(b) violation, without regard to what investors knew or should have known. The two-year period only bars claims that could and should have been brought earlier and preserves claims of "injured investors who by no conceivable standard of fairness or practicality c[ould] be expected to file suit" earlier. *Lampf*, 501 U.S. at 377-78 (Kennedy, J., dissenting).

II. Merck seeks to rewrite §1658(b)(1) so that "information sufficiently suggestive of wrongdoing," Br. 20, starts the limitations period without regard to whether (a) the "wrongdoing" suggests securities fraud or (b) investors should or even could have discovered the facts constituting a §10(b) violation. Merck's standard is contrary to more than a century of this Court's constructive-discovery jurisprudence and benefits those defendants who are best at hiding their fraud.

A. Merck's proposed test omits the requirement that the "means of knowledge" must be "accessible" to the fraud victim. *Burke v. Smith*, 83 U.S. (16 Wall.) 390, 401 (1873). Merck relies on numerous cases

from this Court that turn on the ability of a reasonable person to have actually discovered the fraud, but fails to address this fundamental requirement.

B. Merck's argument that the limitations period should begin with "information sufficiently suggestive of wrongdoing," Br. 20 (which they define as "inquiry notice," Br. 40), misconstrues inquiry-notice principles and lacks support in precedent. Moreover, it cannot be reconciled with §1658(b)(1)'s plain language: "the facts constituting the violation" are not the same as information that would merely trigger a duty to inquire.

Merck's alternative argument that the limitations period should still begin with "information sufficiently suggestive of wrongdoing," with an extension for an actual diligent inquiry, Br. 43, also ignores §1658(b)(1)'s text. This argument treats §1658(b)(1) as if it contained a statutory deadline that courts might equitably extend through judicially created equitable tolling – a doctrine that is "the exception, not the rule." *Rotella v. Wood*, 528 U.S. 549, 561 (2000). In §1658(b)(1), Congress adopted the opposite approach: "discovery of the facts constituting the violation" is the rule, not the exception. Moreover, Merck's own equitable-tolling and fraudulent-concealment cases measure diligence by what the injured party reasonably should have known.

The only cases supporting Merck's forfeiture approach are recent Second and Third Circuit decisions. The Second Circuit cited no legal support for its recent "rule," and the Third Circuit (based on analysis and policies applicable to RICO, not §10(b)) acknowledged it was departing from the rule followed in other circuits that turn on what reasonable investors would have discovered had they inquired.

C. Merck's argument that "hypothetical inquiries about what a reasonably diligent investigation would have entailed" would pose "grave difficulties," Br. 50, is without foundation. Juries and courts, including this Court, routinely resolve questions of what reasonable persons would have done under virtually limitless circumstances, including in the context of traditional constructive-discovery rules. This inquiry will often involve mixed questions of law and fact that are most appropriately left to a jury.

D. Merck also argues that scienter is not among the facts constituting a §10(b) violation and that the Third Circuit erred by adopting a contrary rule. Br. 22. However, the Third Circuit adopted no such rule here: it held simply that respondents had no reason even to suspect that Merck's statements of opinion were false until October 2003 at the earliest. This Court can affirm on that basis.

If the Court reaches the issue of whether facts constituting the violation include scienter, it should hold that it does. Scienter is an essential element of a §10(b) violation, and facts giving rise to actual or constructive discovery of scienter are essential to trigger the running of the statute. Merck's argument that scienter is often proved through circumstantial evidence misses the point. Circumstantial facts can provide investors with sufficient basis to conclude that a defendant's misconduct was committed with scienter; but, where no such facts exist, scienter cannot be inferred, and the statute does not run.

E. Merck argues that by 2002 there was a settled rule that the limitations period should commence with "information sufficiently suggestive of wrongdoing" and that Congress "ratified" that purported rule in enacting §1658(b)(1). As Merck's own petition

to this Court argued, however, there was no such consensus in 2002.

III.A. The Third Circuit correctly held that, as of November 6, 2001, respondents had no reason to suspect Merck's statements of belief in the naproxen hypothesis were even false. As of that date, no publicly available information suggested that Merck's stated belief in the naproxen hypothesis was not sincerely held or lacked reasonable basis. The naproxen hypothesis's validity was publicly debated, but nothing in the public domain would have led a reasonable investor to suspect that Merck was promoting that hypothesis as part of a fraud.

DDMAC's September 2001 letter did not suggest that the naproxen hypothesis lacked reasonable basis or that Merck did not genuinely believe in it. To the contrary, it stated, as had members of FDA's AAC previously, that the hypothesis was a reasonable explanation of VIGOR's results. The letter chastised Merck for violating FDA marketing regulations that required every Vioxx promotional statement to consumers and medical professionals to repeat that the naproxen hypothesis was unproven and that another possible explanation for VIGOR's results was that Vioxx increased the risk of cardiovascular events. That alternate explanation was always well-known to financial markets, and thus a reasonable investor would have found nothing new or material in the letter. Likewise, the consumer tort lawsuits filed before November 6, 2001, provided no new material information to investors.

B. Even assuming arguendo that respondents should reasonably have suspected fraud before November 6, 2001, §1658(b)(1)'s two-year discovery period could not have begun to run because investors

lacked the means to discover the fraud through reasonable inquiry. Merck has never identified anything that its investors should or could have done to discover its fraud before that date. The previously available public information provided no facts upon which a reasonable investor would have concluded that Merck violated §10(b). The critical facts and relevant documents were under Merck's exclusive control.

Accordingly, the court below correctly rejected Merck's contention that, as a matter of law, the limitations period was triggered more than two years before respondents filed the first securities-fraud complaint.

ARGUMENT

I. THE LIMITATIONS PERIOD BEGINS WITH DISCOVERY OF THE ELEMENTS OF A VIOLATION, INCLUDING SCIENTER

Section 1658(b)(1)'s two-year limitations period begins with "the discovery of the facts constituting the violation." 28 U.S.C. §1658(b)(1). This Court interprets §1658(b)(1) by assuming "the ordinary meaning of that language accurately expresses the legislative purpose." *Gross v. FBL Fin. Servs., Inc.*, 129 S. Ct. 2343, 2350 (2009) (internal quotations omitted).

A. The "Violation" Referenced In §1658(b)(1) Is A Violation Of §10(b)

1. The elements of a §10(b) violation are well-established

All parties agree that the "violation" here is a violation of §10(b) of the 1934 Act and SEC Rule 10b-5 promulgated thereunder. In a misrepresentation case, §10(b) is violated when a defendant has (1) made a misrepresentation (2) that is material,

(3) with scienter, (4) in connection with the purchase or sale of securities. *See* 17 C.F.R. §240.10b-5(b) (prohibiting, *inter alia*, "any *untrue statement* of a *material* fact") (emphases added); *Aaron v. SEC*, 446 U.S. 680 (1980) (holding that *scienter* is an essential element of a violation). Investors therefore have not "discover[ed]" enough "facts [to] constitut[e] [a] violation" unless each of those elements is present.[6]

Although the substantive content of the falsity, materiality, and scienter elements of a §10(b) violation is well-settled, a brief summary of those elements helps to place in context the parties' dispute over *when* investors should have discovered Merck's §10(b) violation.

First, the federal securities laws recognize that two types of misrepresentations can violate §10(b): misrepresentations of historical or current facts, such as a company's reported earnings, and misrepresentations of "reasons, opinions, or beliefs." *Virginia Bankshares*, 501 U.S. at 1091. Statements of opinion are "factual in two senses": they are statements that the speaker does "hold the belief stated" and "statements about the subject matter of the reason or belief expressed." *Id.* at 1092. Thus, in a case alleging misrepresentation of belief, as here, it must be "a misstatement of the psychological fact of the speaker's belief in what he says" and must "also mislead about the stated subject matter," *id.* at 1095,

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[6] Under Rule 10b-5, a private investor must also prove reliance, economic loss, and loss causation. *See Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 128 S. Ct. 761, 768 (2008). Because there could not have been discovery of the elements of a §10(b) *violation*, the Court need not decide whether §1658(b) requires separate discovery of these additional elements of a private *cause of action* to trigger the limitations period.

because it lacks the "factual basis that justifies [the opinion] as accurate," *id.* at 1093, or is otherwise "false or misleading in what the statement expressly or impliedly declare[s] about its subject," *id.* at 1095-96.

Second, only "material" misstatements violate §10(b), *i.e.*, misstatements that would be "viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic*, 485 U.S. at 231-32 (internal quotations omitted). *Third*, "scienter is a necessary element of a violation of §10(b) and Rule 10b-5." *Aaron*, 446 U.S. at 695. Investors lacking reasonable basis to believe that a defendant acted with scienter have not discovered a §10(b) violation.

2. *The "facts constituting" a violation are those that establish its elements*

The phrase "facts constituting [a] violation" derives from longstanding ordinary and legal usage of similar language and indicates the appropriate contents of a pleading seeking judicial relief. In ordinary usage, to "constitute" a thing is "to make [it] up, as being the constitutive element or elements." *Webster's New International Dictionary of the English Language* 571-72 (2d ed. 1953). The "facts constituting [a] violation" are thus most naturally its elements. Judicial usage comports with that ordinary meaning. For example, many "constitutional protections turn on determining which facts constitute the 'crime' – that is, which facts are the 'elements' or 'ingredients' of a crime." *Apprendi v. New Jersey*, 530 U.S. 466, 500 (2000) (Thomas, J., concurring).

The language the 1934 Congress enacted in §9(e) was not new. The phrase "facts constituting" appeared in connection with the facts required for

proof at trial, *see, e.g.*, *Harding v. Robinson*, 166 P. 808, 810 (Cal. 1917); criminal indictments, *see, e.g.*, *Brown v. State*, 42 S.E. 795, 796 (Ga. 1902); and pleading, including the "highly influential" pleading model of the day, New York's Field Code of 1848, which required litigants to provide a "statement of the facts constituting the cause of action." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 574 (2007) (quoting Field Code of 1848, ch. 379, §120(2), 1848 N.Y. Laws pp. 497, 521)[7]; *see also* Fed. R. Crim. P. 7(c)(1) (requiring information or indictment to contain "the essential facts constituting the offense charged").

In fraud actions, the courts commonly interpreted the phrase "facts constituting" as those facts that, if proved, would establish all elements of a fraud, including scienter. *See, e.g.*, *Martin v. Smith*, 16 F. Cas. 896, 901 (C.C.D. Mo. 1870) ("If a party knows the facts constituting the fraud, he knows the transaction to be fraudulent. It is not enough simply that he is aware of the fact of the transfer, but he must know 'the facts' which make that transfer fraudulent.") (cited with approval in *Wood*, 101 U.S. at 141).[8] For limitations periods triggered by discovery of "'the facts constituting the fraud,'" courts long have held that "the limitation begins to run as

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[7] The Federal Rules of Civil Procedure were promulgated in 1938.

[8] *See also, e.g.*, *Guy v. Blue*, 45 N.E. 1052, 1053 (Ind. 1897) (in order to show "facts constituting [a] fraud," the "intention to deceive must appear"); *West Virginia Hotel Corp. v. W.C. Foster Co.*, 132 So. 842, 846 (Fla. 1931) (the "essential facts constituting the fraud" must give a "real foundation . . . for the charge of fraud"); *Harding*, 166 P. at 810 ("The material ingredient of actual fraud is the fraudulent intent, and this must be charged as one of the facts constituting the fraud.").

against the plaintiff when he has knowledge of facts which would have impressed a reasonable man with the belief that the transaction was fraudulent." *Martin*, 16 F. Cas. at 902; *see also Higgins v. Crouse*, 42 N.E. 6, 7 (N.Y. 1895) (contrasting the "suspicion" that "suggest[s] the need of an inquiry" with the "decided inference of fraud" that amounts to discovery); 2 Calvin W. Corman, *Limitation of Actions* §11.5.7, at 203 (1991) ("Suspicion that a fraud has been perpetrated . . . should not be equated with knowledge of facts that point to the actual existence of fraud.").

Therefore, as used in §1658(b)(1), the most natural reading of "facts constituting" refers to those facts that, if proved, would establish that the defendant violated §10(b), *i.e.*, made a material misrepresentation or omission with the intent to deceive.

B. "Discovery" Of Facts Occurs When Those Facts Were Or Should Have Been Known

In ordinary usage, "discovery" occurs when one has "f[ound] out or ascertain[ed] the existence of something previously unknown or unrecognized," *Webster's Second* at 745 – that is, when one has acquired actual knowledge of a fact. A plain reading of §1658(b)(1), therefore, would start the limitations period with an investor's *actual* discovery of the elements of Rule 10b-5 violation. Further, a comparison of §1658(b)(1) (and its predecessor, §9(e)) to 1933 Act §13 shows that Congress knew how to create a limitations period that ran after "discovery should have been made by the exercise of reasonable diligence," 15 U.S.C. §77m, when it meant to do so.

Although the Court could affirm on such a plain reading of the statute, the word "discovery" also can be construed as incorporating a principle of *constructive* discovery through "accumulated . . . legal tradi-

tion and meaning." *Morissette v. United States*, 342 U.S. 246, 263 (1952). By 1934, when Congress originally enacted §9(e), many state statutes provided for commencement of a limitations period for fraud with the "discovery . . . of the fact constituting the fraud." John P. Dawson, *Undiscovered Fraud and Statutes of Limitation*, 31 Mich. L. Rev. 591, 591 n.1 (1933) (listing 32 states). The word "discovery" was "everywhere taken to mean something less than *actual* discovery of the defendant's wrong: the wrong is 'discovered' at the point where the facts *could have been ascertained* by using *reasonable* diligence." *Id.* at 619 & n.77 (emphases added) (collecting cases).[9]

This Court's cases also had recognized a constructive-discovery principle well before 1934 applying the traditional equitable discovery rule that, "where relief is asked on the ground of actual fraud, especially if such fraud has been concealed, time will not run in favor of the defendant until the discovery of the fraud, or until, with reasonable diligence, it might have been discovered." *Kirby v. Lake Shore & M.S. Ry. Co.*, 120 U.S. 130, 136 (1887).[10] That rule has

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[9] *See also, e.g., Silva v. Menderson*, 17 P.2d 809, 810 (Ariz. 1933) ("This statute is not peculiar to Arizona. Its counterpart exists in many of the states . . . . [I]f the facts and circumstances were such *as in the exercise of reasonable care and diligence he should have discovered the fraud*, he is deemed to have notice."); *Duxbury v. Boice*, 72 N.W. 838, 839-40 (Minn. 1897) (same; also observing similarity to other statutes).

[10] *See also Amy v. City of Watertown*, 130 U.S. 320, 324 (1889) ("The courts of equity, . . . from an early day, held that where one person has been injured by the fraud of another, and the facts constituting such fraud do not come to the knowledge of the person injured until some time afterwards, the statute will not commence to run until the discovery of those facts, or until by reasonable diligence they might have been discovered."); *Duxbury*, 72 N.W. at 839 (quoting the English statute of 3 & 4

continued through the present. *See, e.g., TRW Inc. v. Andrews*, 534 U.S. 19, 30 (2001) (under a discovery rule, limitations period begins running when "a reasonable person in [the plaintiff's] position would have learned of the [fact to be discovered] in the exercise of due diligence").

The term "discovery," however, does not extend to encompass information an investor neither knew nor would have learned through reasonable diligence. *See id.* (quoting 2 Corman §11.1.6, at 164: "It is obviously unreasonable to charge the plaintiff with failure to search for [a] missing element of [a] cause of action if such element would not have been revealed by such search."). Accordingly, no plausible interpretation of §1658 would permit the limitations period to commence at a time when investors neither knew nor should have known facts constituting a §10(b) violation.

C. "Inquiry Notice," Properly Understood, Is Only A Part Of The Doctrine Of Constructive Discovery

The principle of "inquiry notice" posits that a party who has enough information "'to excite attention and put the party on his guard and call for inquiry'" is considered on "'notice of every thing to which such inquiry might have led.'" *Wood*, 101 U.S. at 141 (quoting *Kennedy v. Greene*, 3 Myl. & K. 722 (Ch. 1834)). Similarly, in *Higgins*, the court interpreted the phrase "discovery . . . of the facts constituting the fraud" in New York's statute of limitations, explaining that one who "know[s] sufficient [facts] to fairly

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Wm. IV, c. 27, §26, and holding that a claim is "'deemed to have first accrued *at and not before* the time at which such fraud shall, or with reasonable diligence might have been, first known or discovered'") (emphasis added).

arouse suspicion" in a case where "reasonable and natural action would reveal the truth and disclose the fraud" will be charged with "the knowledge which he ought to have had, and would have had if he had done his duty." 42 N.E. at 7.

Inquiry notice is thus part of, not separate from, a retrospective constructive-discovery analysis that focuses on what investors should have known.[11] Investors exercising reasonable diligence to protect their rights will occasionally obtain information suggesting possible fraud. If investors have "means of knowledge accessible" for obtaining more information about possible fraud, reasonable diligence then requires use of those means. *Burke*, 83 U.S. at 401. If reasonable further inquiry would reveal additional information of fraud, then the investor will be "held to have known" that information. *Wood*, 101 U.S. at 141. At every stage of the analysis, however, the question remains what "a reasonable person . . . *would have learned* . . . in the exercise of due diligence." *TRW*, 534 U.S. at 30 (inquiry notice applies "only if" reasonable person would have learned relevant facts) (emphasis added).

1. Inquiry notice begins with a reason to inquire about fraud

In securities cases, courts colorfully have referred to facts that would "alert a reasonable investor to the possibility of fraudulent statements or omissions

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[11] For example, "investors are presumed to have read prospectuses, quarterly reports, and other information relating to their investments," whether or not they had a specific reason to inquire. *Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239, 252 (3d Cir. 2001). That type of information usually provides the predicate for asking whether an investor should then have inquired further. *See id.*

in his securities transaction" – thereby triggering a duty to inquire – as "storm warnings." *E.g.*, *Jensen v. Snellings*, 841 F.2d 600, 607 (5th Cir. 1988). Merck does not quarrel with that general statement of the standard, *see* Br. 21 & n.4, and neither do respondents. That duty to inquire ordinarily marks the beginning point for the court's retrospective constructive-knowledge analysis.

Importantly, a judicial finding that an investor should have made inquiry is a legal conclusion that the failure to inquire constituted negligence. *See, e.g.*, *Foster v. Mansfield, C. & L.M.R.R. Co.*, 146 U.S. 88, 99-100 (1892) (question is whether "negligence is imputable to [plaintiff] for failing to inform himself of his rights"); *cf. Higgins*, 42 N.E. at 7 (party "is not negligent for failing to enter upon an investigation which no fact within his knowledge indicates to be necessary or prudent"). Dismissal on the pleadings on an inquiry notice theory without any fact-findings, therefore, represents a judgment that the plaintiffs have pleaded facts establishing their own negligence as a matter of law. That should be a heavy burden for any defendant to establish, and Merck cannot meet it in this case.[12]

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[12] Absent clear-cut circumstances, most courts reserve for a jury issues of when "discovery of facts constituting the violation" should be deemed to have occurred. *See Gurley v. Documation Inc.*, 674 F.2d 253, 259 (4th Cir. 1982); *Kennedy v. Tallant*, 710 F.2d 711, 716 (11th Cir. 1983); *see also Staehr v. Hartford Fin. Servs. Group, Inc.*, 547 F.3d 406, 425-26 (2d Cir. 2008) (citing 5 Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* §1226 (3d ed. 2004), for the proposition that, because a time-bar is an affirmative defense under federal law, a complaint can be dismissed on limitations grounds only for a defect that appears on its face).

2. Inquiry notice requires the means of discovering the facts constituting the violation

Information calling for inquiry, however, is not sufficient by itself to commence the limitations period. Even once a party learns facts "sufficient to put her on inquiry, she can only be charged with knowledge of the facts which she might have learned by inquiry." *Indiana & I.C. Ry. Co. v. Sprague*, 103 U.S. 756, 762 (1881); *see also Wood*, 101 U.S. at 141 (plaintiff must have "the means of discovery in his power" to be on inquiry notice).[13] Prior to 1934, states that adopted statutes running the limitations period from "discovery" of the facts constituting the fraud uniformly offered similar interpretations. *See* 2 H. Wood, *Limitations of Actions* §276b(12), at 1403-05 (4th ed. 1916).[14] Seventy-five years after Congress adopted 1934 Act §9(e)'s "discovery rule," that time-honored principle remains unchanged. *See TRW*, 534 U.S. at 30 ("The duty of inquiry having arisen, plaintiff is charged with whatever knowledge an inquiry would have revealed.") (internal quotations omitted).

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[13] *See also Burke*, 83 U.S. at 401 (plaintiff must be "put upon inquiry with the means of knowledge accessible to him"); *Kirby*, 120 U.S. at 139 (quoting *Burke*); *Oliver v. Piatt*, 44 U.S. (3 How.) 333, 410 (1845) (purchaser who was "positively put upon inquiry" with regard to validity of title also had "most ample means of knowing the nature and character and extent of the title").

[14] *E.g.*, *Consolidated Reservoir & Power Co. v. Scarborough*, 16 P.2d 268, 269 (Cal. 1932); *Richardson v. Mounce*, 19 S.C. 477, 1883 WL 4905, at *4 (S.C. 1883); *O'Dell v. Burnham*, 21 N.W. 635, 639 (Wis. 1884); *Parker v. Kuhn*, 32 N.W. 74, 82 (Neb. 1887); *Brown v. Irving-Pitt Mfg. Co.*, 292 S.W. 1023, 1025 (Mo. 1927); *Ray v. Divers*, 264 P. 673, 675 (Mont. 1928).

Accordingly, if information that led to a duty to inquire by investors would not lead to discovery of facts from which a reasonable person would infer fraud, inquiry notice of "the facts constituting the violation" has not occurred. *Wood*, 101 U.S. at 141 (inquiry notice applies when party has "sufficient information to lead him to a [relevant] fact") (internal quotations omitted). For example, if defendants have successfully concealed the facts necessary to discover "facts constituting" the fraud, or provide legitimate explanations for the circumstances that excited inquiry, a court looking backward will not conclude that the plaintiff was on inquiry notice of the true, unavailable facts. *See Sprague*, 103 U.S. at 763 (refusing to impute bad faith to bond investor because any further inquiry made "would have afforded a most satisfactory explanation").

This Court's cases illustrate what sort of inquiry is reasonable. Commonly, plaintiffs are charged with reviewing documents to which they have ready access. *See Burke*, 83 U.S. at 401 (reasonable for creditors with access to corporate records to inspect privately held company's books, which would have uncovered the alleged fraud).[15] Similarly, plaintiffs may be charged with knowledge of readily accessible public records and proceedings. *See Wood*, 101 U.S. at 139-40.[16] Plaintiffs also may be charged with

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[15] *See also Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997) (Posner, J.) (applying an inquiry-notice analysis where "[all necessary information] was in documents that were in the possession of the victim itself"); *Prentiss v. McWhirter*, 63 F.2d 712, 714 (9th Cir. 1933) (construing California's statutory discovery rule).

[16] *See also Redd v. Brun*, 157 F. 190, 194 (8th Cir. 1907) (finding laches where allegedly fraudulent deeds were "spread upon the public records").

knowledge obtainable from readily accessible and identifiable third parties. *See, e.g., Foster*, 146 U.S. at 100 (reasonable to interview dissident directors who protested allegedly fraudulent conduct); *Wood*, 101 U.S. at 141 (reasonable to confirm with third parties whether funds intended for them had been diverted).

Plaintiffs are not, however, charged with knowing facts exclusively within a defendant's control. Merck cites no case where this Court has presumed that plaintiffs would be able to uncover such facts, and it would be inconsistent with the universal rule that the "means of discovery" must be in the *plaintiff's* hands. *Wood*, 101 U.S. at 141; *see Law v. Medco Research, Inc.*, 113 F.3d 781, 786 (7th Cir. 1997) (dismissing as not "serious" suggestions that plaintiffs "should have hired a lawyer to investigate, called their broker, or called Medco").[17]

In sum, plaintiffs are not deemed to have "discover[ed] the facts constituting the violation" when they neither could nor should have known them through reasonable diligence. When the facts constituting a violation are unavailable, the fraud could not have been discovered, and the two-year limitations period is not triggered.

D. Statutory Structure Confirms A Focus On What Was Or Should Have Been Known

The context and structure of §1658(b)(1) confirm that Congress intended "discovery of the facts consti-

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[17] *See also Fujisawa*, 115 F.3d at 1335 (in applying inquiry-notice doctrine, court should "bear[] in mind that before [the plaintiff] files his suit he will not have the aid of compulsory process"); *Cunningham v. Pettigrew*, 169 F. 335, 343 (8th Cir. 1909) (declining to assume that defendants would "voluntarily give self-inculpating evidence").

tuting the violation" of §10(b) to be the date on which an investor knew or should have known of facts establishing each element of the violation. Section 1658(b)(1)'s two-year limitations period appears alongside a five-year repose period established by §1658(b)(2). That five-year period runs from the date of the "violation" itself (which, as Merck agrees (at 29-30), is the date of the material misstatement made with scienter). A resourceful defendant can thus conceal the facts constituting its fraud for a sufficient time that a reasonably diligent plaintiff would be time-barred. To do so, however, the defendant must wait five years, not two.

A statute of limitations that incorporates the discovery rule aims "to ensure a fair balance between protecting the legitimate interests of aggrieved investors, yet preventing stale claims." *Lampf*, 501 U.S. at 378 (Kennedy, J., dissenting). It preserves the claims of "injured investors who by no conceivable standard of fairness or practicality can be expected to file suit" earlier than they did. *Id.* at 377. A statute of repose, by contrast, represents the legislature's judgment that, after the repose period, "important considerations of fairness" to defendants, such as likely loss of evidence, outweigh even the loss of meritorious claims through no fault of a plaintiff. *Id.* at 378.

Congress's inclusion of both types of provisions in §1658(b) (and, earlier, in §9) shows the balance it struck. A claim is barred by the two-year period only if it could and should have been brought earlier. A claim may be barred by the five-year period regardless of when it could have been brought, to eliminate the possibility that claims would persist indefinitely because a plaintiff never learns of them. Merck's

extensive discussion of the evils of stale claims and the need to encourage greater diligence – even at the "cost" of foreclosing fraudulently concealed meritorious claims (Br. 32) – nowhere addresses §1658(b)(2) or its plain implication that Congress considered and articulated the circumstances where a truly aggrieved and diligent plaintiff could not recover. This Court should reject Merck's invitation to obstruct the objectives Congress sought to achieve.

II. NEITHER TEXT NOR PRECEDENT SUPPORTS MERCK'S INVENTED STANDARD

Merck asks this Court to redraw the line between the limitations and repose periods in a manner inconsistent with the statute's plain text, which nowhere suggests that the statute begins before the discovery of facts constituting a violation of §10(b). Merck's proffered rule would require every investor to launch an investigation of unspecified content, cost, and duration of even publicly traded (and widely scrutinized) companies based on "a quantum of information sufficiently suggestive of wrongdoing." Br. 20. That rule would impute discovery of a §10(b) violation to investors without any showing that they should or even could have discovered the facts constituting the violation. Br. 42-43.

Merck maintains that, while its public statements promoting the validity of the naproxen hypothesis were persuading doctors to write billions of dollars in Vioxx prescriptions, investors all along should have known better than medical professionals and disbelieved the very representations that supported Merck's lucrative sales of its blockbuster drug. Merck's rule thus most benefits those who are best at hiding their fraud. More than a century ago, this Court rejected such an approach, refusing to read a

statute of limitations for fraud so as to "make the law which was designed to prevent fraud the means by which it is made successful and secure." *Bailey v. Glover*, 88 U.S. (21 Wall.) 342, 349 (1875). This Court should do the same here.

A. Inquiry Notice Does Not Exist Without Means To Inquire

Merck claims that inquiry notice exists when "a plaintiff possesses a quantum of information sufficiently suggestive of wrongdoing that he should conduct a further inquiry to confirm the existence of his claim." Br. 20. That statement lacks grounding in this Court's cases, which define inquiry notice as attaching only after a plaintiff has been "put upon inquiry *with the means of knowledge accessible to him*." *Burke*, 83 U.S. at 401 (emphasis added); *see supra* pp. 30-31 & n.13. Where an investor could not have discovered the fraud, penalizing the failure to engage in an objectively futile inquiry and marking the date when "inquiry" should have occurred make no sense.

Although Merck relies upon *Burke*, *Kirby*, and *Wood*, it nowhere mentions those cases' consistent theme that inquiry notice is based on an investor's *ability* to discover the relevant facts – much less the similar points the Court made in *Foster* and *Sprague*. *See supra* pp. 30-32. Nor does Merck deal with the Court's repeated analysis in those cases of particular inquiries that fraud victims could and should have made and the results those inquiries would have achieved. *See supra* pp. 31-32. Similarly, Merck relies on *TRW* for the proposition that "a plaintiff could be on inquiry notice without possessing information specifically relating to each element . . . of the violation," Br. 21-22, but omits *TRW*'s much more telling statement that the plaintiff in that case would be "on

'inquiry notice' . . . *only* if a reasonable person in her position *would have learned* of [her] injury in the exercise of due diligence," 534 U.S. at 30 (emphases added).[18] Merck's patchwork of selective quotations undercuts its entire theory of the case.[19]

B. Mere Suspicion Of Wrongdoing Does Not Commence The Limitations Period

1. Merck offers two alternative arguments linking the date on which plaintiff receives information merely suggestive of some kind of wrongdoing to the

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[18] Merck also leaves out *TRW*'s approving quotation of Professor Corman's statement that "'[i]t is obviously unreasonable to charge the plaintiff with failure to search for the missing element of the cause of action if such element would not have been revealed by such search,'" 534 U.S. at 30 (quoting 2 Corman §11.1.6, at 164), which is directly on point and contrary to Merck's position.

[19] Cases cited by Merck make the same point. *See Association of Commonwealth Claimants v. Moylan*, 517 N.W.2d 94, 102 (Neb. 1994) ("[D]iscovery occurs when the party knows of facts sufficient to put a person of ordinary intelligence and prudence on inquiry which, if pursued, *would lead to the discovery* of facts constituting the basis of the cause of action.") (emphasis added), *cited at* Br. 40; *Teall v. Slaven*, 40 F. 774, 778 (N.D. Cal. 1889) (quoting extensively from *Wood*), *cited at* Br. 44 n.12; *Andrews v. Dole*, 1 F. Cas. 878, 884 (D.N.J. 1875) ("[T]he postponement is not until the discovery of the fraud, but until the period of time when, with due diligence, he *might have discovered* it.") (emphasis added), *cited at* Br. 44 n.12; *Holman v. Hansen*, 773 P.2d 1200, 1203 (Mont. 1989) (inquiry notice means "notice or information of circumstances which would put [one] on inquiry which if followed *would lead to knowledge*") (internal quotations omitted; emphasis added), *cited at* Br. 40; *Blegen v. Monarch Life Ins. Co.*, 365 N.W.2d 356, 357 (Minn. Ct. App. 1985) ("[A] party must be deemed to have discovered the fraud when, in the exercise of proper diligence, he *could and ought to have discovered* it.") (internal quotations omitted; emphasis added), *cited at* Br. 25.

date that the limitations period for a §10(b) violation commences. *First,* Merck contends "the date on which the plaintiff was on inquiry notice" – defined as the receipt of suggestive information – should "always trigger the running of the limitations period." Br. 40. That contention cannot be squared with the statutory text. The words "discovery of the facts constituting the violation" do not mean "possess[ion] [of] a quantum of information sufficiently suggestive of wrongdoing that [one] should conduct a further inquiry." Br. 20.[20] By Congress's direction, the limitations period begins with the former, not the latter.[21]

Merck offers no case from this Court adopting the Draconian rule that information "suggestive of wrongdoing" puts a party immediately on constructive notice of all elements of its claim. Indeed, it is well-established that a plaintiff "must [have] more than mere suspicion" before being charged with "knowledge of fraud as a matter of *law*." 2 Corman §11.5.1, at 185. The case Merck touts as stating the "traditional[] operat[ion]" of inquiry notice, *Wood*, merely holds that, "'[w]hatever is notice enough to . . . call for inquiry, is notice of every thing to which such inquiry *might have led*.'" Br. 39-40 (quoting 101 U.S. at 141) (emphasis added). But Merck never identifies what facts investors here could have discovered through a reasonable inquiry in the period

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[20] Indeed, Merck itself concedes that its proposed standard is *not* the same as "discovery" – if inquiry notice does not attach before "[a] plaintiff . . . could . . . be said to have *discovered* his claim," then "the doctrine of inquiry notice would effectively do no work." Br. 23.

[21] Merck's rule also cannot be reconciled with Congress's inclusion of an express constructive-discovery provision in 1933 Act §13 and its omission of one from §1658(b)(1). *See supra* p. 25 (quoting 15 U.S.C. §77m).

from September to November 2001 that "might have led" them to the facts constituting a §10(b) violation. Merck therefore cannot prevail under *Wood*'s standard. *See infra* pp. 54-55.

Second, perhaps recognizing that its proposal lacks foundation in §1658(b)'s text, Merck offers an alternative formulation under which a "plaintiff should be entitled to an additional period of time before the limitations period commences only when he conducts a reasonably diligent investigation." Br. 43. That, as Merck concedes (at 46), is "functionally equivalent" to an ordinary equitable-tolling analysis, which is a judicially created rule based on the assumption that a court may equitably extend a statutory deadline in a small number of cases: it is "the exception, not the rule." *Rotella*, 528 U.S. at 561. In §1658(b)(1), Congress adopted the opposite approach. It crafted a limitations period starting with discovery of the facts constituting the violation as the rule, not the exception. Placing the burden on plaintiffs in every securities-fraud case to establish an entitlement to equitable tolling literally ignores §1658's text: doing so would create the same legal framework that would apply under an ordinary statute of limitations based on the date of the violation, subject to the usual doctrines of fraudulent concealment and equitable tolling. Congress meant to do something different with §1658(b)(1).

The cases cited by Merck applying nonstatutory equitable doctrines to differently worded statutes do not help it. *See* Br. 43 (citing *Holmberg v. Armbrecht*, 327 U.S. 392, 393-94 (1946); *United States v. Diamond Coal & Coke Co.*, 255 U.S. 323, 332 (1921); *Bailey*, 88 U.S. at 347). Without finding *any* lack of diligence by plaintiffs, those cases all merely stated

in general terms that a plaintiff must be diligent (or at least free of negligence or laches) to take advantage of the discovery rule as a matter of equity. *See Holmberg*, 327 U.S. at 397; *Diamond Coal*, 255 U.S. at 332; *Bailey*, 88 U.S. at 349-50. None held that a plaintiff's suit could be time-barred for lack of diligence without the court first determining that the plaintiff should have discovered the fraud earlier through reasonably available means.[22]

Merck also incorrectly relies on *Klehr v. A.O. Smith Corp.*, 521 U.S. 179 (1997). *Klehr* adopted for civil RICO claims the standard that applies when an antitrust claim has been fraudulently concealed: a plaintiff has not been diligent unless "'he neither knew nor, in the exercise of due diligence, could *reasonably have known* of the [defendant's] offense.'" *Id.* at 195 (quoting 2 Phillip Areeda & Herbert Hovenkamp, *Antitrust Law* ¶338, at 152 (rev. ed. 1995)) (emphasis added). Far from supporting Merck's punitive proposal, *Klehr* merely provides another example where the limitations period begins running no earlier than the date on which plaintiffs should have discovered the relevant facts.

Merck's policy arguments also ignore the substantial waste of resources that its theory would create when (as in this case) the facts constituting the viola-

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[22] *Diamond Coal* in particular undercuts Merck's argument. The district court there had refused the government the benefit of the discovery rule because of alleged laches in discovering the fraud. *See* 255 U.S. at 329-30, 332. This Court rejected that result, explaining that the finding of laches "depend[ed] upon the existence of *knowledge* of . . . *facts*" establishing the fraud or "of knowledge of other facts from which they were reasonably deducible." *Id.* at 334 (emphases added). *Diamond Coal* thus supports respondents' position that the appropriate focus of the discovery rule is what an investor knew or should have known.

tion are not discoverable. On Merck's theory, its investors should have spent time, money, and effort on inquiries – even though Merck continuously provided reassurances that such inquiries were unnecessary – despite the lack of available information. Congress could not have intended such a perverse result, which would be contrary to its policy against the filing of premature federal securities actions lacking a substantial factual basis. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313-14 (2007). To penalize investors in such circumstances (while adding an additional protection to defendants) conflicts with the balance struck by Congress in §1658 between a limitations period based on "discovery" and "repose" after five years.

2. The only cases supporting Merck's forfeiture approach are recent formulations from the Second and Third Circuits. But the Second Circuit has never provided any legal foundation for its "two-track" approach or explained its departure from the traditional discovery rule that it applied in *Armstrong v. McAlpin*, 699 F.2d 79, 88 (2d Cir. 1983) (which had appropriately cited, *inter alia*, *Wood* and *Higgins*). The Third Circuit recognized that it was not adopting the rule followed in other circuits, which based inquiry notice on what a reasonable inquiry, if conducted, would have found. *See Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239 (3d Cir. 2001). The Third Circuit also based its rule on policies applicable to RICO, not §10(b), *see id.* at 253 & n.16, and that analogy is inapt. *See supra* p. 39.

More importantly, Merck's rule cannot be squared with Congress's purpose in enacting §1658 in 2002. Congress sought to expand investor remedies and strengthen deterrence after the Enron and Worldcom

frauds. It is inconceivable that Congress intended to accomplish that result by deeming plaintiffs to have "discovered" facts that were unavailable due to a defendant's own fraud. Nor was Congress likely to anticipate that any court would interpret §1658(b) in such a manner in 2002: *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314 (3d Cir. 2002), the first securities case in which the Third Circuit applied the inquiry notice "rule" it adopted in *Mathews*, had not been decided, and the Second Circuit did not fully articulate its approach until 2003, *see LC Capital Partners, L.P. v. Frontier Ins. Group, Inc.*, 318 F.3d 148, 155-56 (2d Cir. 2003).

C. The Established Constructive-Discovery Standard Presents No Undue Difficulty

Merck argues that its proposed rule avoids "grave difficulties in application" because courts will not have to take into account "hypothetical inquiries about what a reasonably diligent investigation would have entailed." Br. 20, 50. That contention flies headlong into more than a century of precedent. *See, e.g.*, *TRW*, 534 U.S. at 30 (stating that the question is what "a reasonable person . . . would have learned"); *Kirby*, 120 U.S. at 138 (asking when, "with reasonable diligence, [the fraud] might have been discovered"); *Sprague*, 103 U.S. at 762 (explaining that a party "can only be charged with knowledge of the facts which she might have learned by inquiry"); *see also supra* pp. 30-32.

More broadly, a fundamental precept of the common law presumes that "the perspective of the hypothetical 'reasonable person' gives content to concepts such as 'negligent' behavior." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 37 (1997). This Court has applied that principle in constructive-

discovery cases without hesitation. *See, e.g.*, *Foster*, 146 U.S. at 100 (examining inquiries that plaintiff could have made before concluding that "[t]he slightest effort on his part would have apprised him" of the relevant facts); *Wood*, 101 U.S. at 140 (listing inquiries that plaintiff might have made before concluding that "proper diligence could not have failed to find a clew in every case that would have led to evidence not to be resisted"). As Professor Dawson explained, use of a hypothetical inquiry "introduces new variables into the arithmetic of the limitation acts, but it seems imperatively required by their larger social purpose and it is functionally related to the equitable doctrine of 'laches' from which these exceptions are historically derived." Dawson, 31 Mich. L. Rev. at 619-20.

Merck's complaint (at 50) that this longstanding analysis (which is only a variant of the general common-law negligence standard) creates "difficulties" is therefore unpersuasive.[23] When applied to this case, that analysis leads inexorably to the conclusion that a reasonable investor would not have discovered Merck's misrepresentations of belief concerning the naproxen hypothesis before November 6, 2001. Therefore, no constructive discovery (based on inquiry notice, or otherwise) triggered the limitations period to bar respondents' complaint.

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[23] Merck's proposed rule, moreover, does not seem likely to avoid hypothetical inquiries, as Merck presumably would reserve defendants' ability to challenge the "reasonableness" of any inquiries actually undertaken by or on behalf of an inquiring plaintiff by comparing them to what more a hypothetical reasonable investor would have done.

D. The "Facts Constituting [A] Violation" Under §1658(b) Include Scienter

Merck also would have this Court declare as a matter of law that any misstatement of fact made in the securities context – even without any indication that it was made with an intent to deceive – triggers inquiry notice of fraud. Br. 22-23. There is no basis to interpret §1658(b) to exclude scienter when the violation referenced in §1658(b) encompasses "fraud, deceit, manipulation, or contrivance," all of which inherently connote scienter. *See Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164 (1994); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 197 (1976). *See supra* pp. 21-25.

Merck incorrectly (and without citing the decision below) characterizes the Third Circuit as adopting a "bright-line rule that a plaintiff who possesses information that the defendant made a misstatement can *never* be on inquiry notice until he also possesses discrete information specifically relating to scienter." Br. 22. That mischaracterizes the opinion of the Third Circuit, which decided this case (as can this Court) solely on the ground that the *falsity* of Merck's statements could not have been known until, at the earliest, October 2003. Pet. App. 47a. Thus, this Court should decline Merck's invitation (at 39) to reverse a rule that the Third Circuit did not adopt below.

If the Court reaches the question, however, it should hold that, because scienter is an element of a §10(b) violation, actual or constructive knowledge of scienter is essential to trigger the running of the statute. *See supra* pp. 25-27. Merck's argument (at 22) that evidence of scienter "is usually proved through inferences from circumstantial evidence"

misses the point. That scienter can be inferred from sufficient circumstantial evidence does not compel the conclusion that Congress intended the statute to eliminate the need for any such inference before the two-year limitations period begins. In some cases, where the circumstances surrounding a misstatement *do* suggest scienter, those circumstances will furnish the necessary information. But in circumstances, as here, that do not indicate a defendant's intent to deceive, an investor cannot be penalized for failing to intuit scienter.

Merck contends that, under *United States v. Kubrick*, 444 U.S. 111 (1979), *Klehr*, and *Rotella*, investors need not have suspicion of fraud before they have a duty of inquiry. Br. 25-27. However, none of these cases involved statutes with an explicit discovery rule, let alone one that embraced the elements of the violation. *See supra* p. 39 (discussing *Klehr*); *Kubrick*, 444 U.S. at 113 n.1 (quoting 28 U.S.C. §2401(b)). *Rotella* involved whether the RICO statute of limitations, which is triggered by a plaintiff's "injury," would be tolled pending discovery of a "pattern" of racketeering. The Court concluded there that fraud "is generally associated with a different accrual rule." 528 U.S. at 557. In *TRW*, the Court suggested that a plaintiff who discovers she was improperly denied credit would have a reason to suspect *negligence*, not necessarily *willfulness*. *See* 534 U.S. at 29-30. It is far more reasonable to suspect *negligence* from an error than to adopt a blanket rule that all errors raise a suspicion of fraud.

Indeed, Merck's proposed rule generally is inconsistent with the concept of discovery, which only requires parties to behave with "ordinary care and attention," *Wood*, 101 U.S. at 141 (internal quota-

tions omitted), and does not require investors to see fraud in every shadow.

E. Congress Never "Ratified" Merck's Version Of Inquiry Notice

Merck claims (at 20) that, in enacting §1658(b), Congress "ratified [the] understanding" that "the Section 9(e) limitations provision, as applied to Section 10(b) actions, incorporated . . . the principle of inquiry notice." Merck's reliance on *Berry v. Valence Technology, Inc.*, 175 F.3d 699 (9th Cir. 1999), however, is misplaced. That case expressly *declined* to "decide whether actual discovery or inquiry notice applies" to Rule 10b-5 actions and criticized other appellate court decisions as "contrary to the specific guidance issued by the Court" in *Lampf*. *Id.* at 704 (internal quotations omitted); *see also id.* at 703.

Even if the lower courts uniformly had agreed that §9(e) incorporated a concept akin to "inquiry notice" before Congress enacted §1658(b), they did not agree *when* inquiry notice should be triggered and what consequences flow from a plaintiff's failure to investigate. As Merck itself concedes (at 39), "courts of appeals have taken conflicting positions as to when the limitations period begins running."[24] Given that

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[24] *See Berry*, 175 F.3d at 704 (noting disagreement among appellate courts and opinion that the statute of limitations begins to run only once the investor "should have discovered the facts underlying the alleged fraud") (internal quotations omitted); *see also Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1201 (10th Cir. 1998) ("limitations period begins to run" not with an investor's "duty to exercise reasonable diligence," but when "the investor, in the exercise of reasonable diligence, should have discovered the facts underlying the alleged fraud"); *Cooperativa de Ahorro y Credito Aguada v. Kidder, Peabody & Co.*, 129 F.3d 222, 225 (1st Cir. 1997) (refusing to decide whether statute of limitations ran from date investors had a duty to inquire about

lack of clarity, "[i]t would thus be impossible to say which view Congress might have endorsed." *United States v. Wells*, 519 U.S. 482, 496 (1997).[25]

The sole piece of legislative history relating to inquiry notice cited by Merck (at 20) is a statement of senators who voted *against* §1658(b). But "[t]he fears and doubts of the opposition are no authoritative guide to the construction of legislation." *Schwegmann Bros. v. Calvert Distillers Corp.*, 341 U.S. 384, 394 (1951). That background, therefore, offers no support for Merck's strained reading of the statute's plain text.

III. THE COMPLAINT WAS TIMELY FILED

The Third Circuit correctly held that Merck cannot establish, as a matter of law, that respondents had a reasonable basis to believe (or, indeed, even to suspect) that Merck had made a material misrepresentation in violation of §10(b) more than two years before the first securities complaint was filed.

A. Respondents Were Not On Inquiry Notice Prior To November 2001

1. Nothing suggested that Merck's statements of opinion were false before November 2001

As the Third Circuit recognized, *see* Pet. App. 33a-34a, and as Merck now concedes, Br. 38, the gravamen of respondents' claims is that Merck falsely represented that it believed that the naproxen

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fraud or on the later date when an investor could have discovered fraud).

[25] Merck's argument suffers even further because Congress nowhere discussed the case law, thereby making this Court's interpretive task "'treacherous.'" *NLRB v. Plasterers' Local Union No. 79*, 404 U.S. 116, 129-30 (1971) (quoting *Girouard v. United States*, 328 U.S. 61, 69 (1946)).

hypothesis was the most likely explanation for VIGOR's results, when internally it actually had concluded the opposite.

As noted above, statements of belief "are factual in two senses: as statements that the [speaker] . . . hold[s] the belief stated and as statements about the subject matter of the reason or belief expressed." *Virginia Bankshares*, 501 U.S. at 1092. Investors had no basis even to suspect before November 6, 2001, that Merck did not believe its hypothesis, or that the hypothesis lacked a reasonable basis. Respondents therefore could not have been on any kind of notice (even under Merck's erroneous standard) that Merck's statements were *false*, let alone that they had violated §10(b).

In 2000 and 2001, Merck investors and the financial community were well aware that VIGOR's results *could* be attributable to a harmful effect of Vioxx rather than to a beneficial effect of naproxen. *See supra* pp. 5-8. Merck's investors were charged with that knowledge. Merck's statements promoting the naproxen hypothesis did not (and were not meant to) lead investors to believe there was *no* possibility Vioxx was harmful. Rather, those statements were meant to (and did) induce investors to believe that Merck, with its particular expertise and intimate knowledge, believed that the most "likely" explanation was that Vioxx was not harmful. Because "[p]robabilities determine the value of stock," *Pommer v. Medtest Corp.*, 961 F.2d 620, 623 (7th Cir. 1992), Merck's opinion was of critical importance. *See Virginia Bankshares*, 501 U.S. at 1091 ("[s]hareholders know that [corporate officers] usually have knowledge and expertness far exceeding the normal investor's resources").

Merck contends that investors had reason to suspect fraud because of publicly available information that "debat[ed] the merits of (and, in many instances, cast[] doubt on) Merck's position that the 'likely' explanation for the disparity in cardiovascular events was that naproxen prevented blood clots." Br. 34. But those debates suggested only that Merck's interpretation of medical data was inconclusive, *i.e.*, that Merck might have been mistaken in its belief in the naproxen hypothesis. More was needed to provide reasonable grounds even to suggest that Merck's stated belief in its naproxen hypothesis was not made in good faith, *i.e.*, was *false*.

The very sources that Merck claims should have created a duty of inquiry expressly accepted the naproxen hypothesis as plausible, suggesting that Merck had a reasonable basis for supporting it.[26] Investors also had no reason to doubt the veracity of Merck's contemporaneous representations that it had additional "very, very reassuring" undisclosed data showing that "VIOXX does not result in any increase

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[26] *See* JA326 (*JAMA* article: VIGOR data "can be explained by either a significant prothrombotic effect from [Vioxx] or an antithrombotic effect from naproxen (or conceivably both)"); JA340 (DDMAC letter: describing the naproxen hypothesis as "a possible explanation" of VIGOR's results); JA504-06 (Oct. 9, 2001 *NYT* article: reciting Merck's unchallenged representation that it had "found no evidence that Vioxx increased the risk of heart attacks" in trials using different comparator drugs or placebo; and presenting issue as one where the available data are insufficient to "fully resolve[]" a scientific debate). Other articles Merck cites also contained unchallenged representations from Merck that its clinical data (outside of VIGOR) showed no disparity in cardiovascular events between Vioxx and non-naproxen NSAIDs or placebo, JA361, 367, 371, or quoted market analysts endorsing the naproxen hypothesis, JA367-68, 370-71.

in cardiovascular events compared to placebo." JA119 (¶214) (responding to *JAMA*'s article).[27] Such reassurances represent "words of comfort" that allay investors' suspicions and can be found to extinguish any "notice" of fraud they might otherwise have had. *Newman v. Warnaco Group, Inc.*, 335 F.3d 187, 194 (2d Cir. 2003) (internal quotations omitted).

In addition, FDA itself confirmed the apparent reasonableness of the naproxen hypothesis on numerous occasions, *e.g.*, in February 2001 (when leading members of an FDA advisory committee stated that the naproxen hypothesis appeared to be the best explanation for VIGOR's results); in DDMAC's September 2001 letter; and in April 2002 when FDA expanded Vioxx's approved uses. JA145 (¶256). A reasonable investor giving "ordinary care and attention" to his investment, *Wood*, 101 U.S. at 141 (internal quotations omitted), was not required to inquire further into whether Merck's own primary regulator was incorrect about the reasonableness of the naproxen hypothesis.

2. Violations of FDA regulations did not suggest a material misstatement of opinion

In its September 2001 letter to Merck, DDMAC charged that certain marketing statements made by a Merck consultant and Merck personnel manning a convention sales booth to approximately 100 doctors and 1,300 pharmacists failed to disclose (i) that Merck's naproxen hypothesis was unproven; and (ii) that another reasonable explanation for VIGOR's results was that Vioxx caused adverse cardiovascular

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[27] *See also* JA95-96 (¶166) (Merck assuring investors that non-public data showed "no difference in the incidence of cardiovascular events . . . among patients taking Vioxx, other NSAIDs and placebo").

events. JA339, 342-46, 351-52. Consistent with the FDA committee's previous position in February 2001, and the agency's later approval of expanded uses in April 2002, DDMAC's letter did *not* contend that the naproxen hypothesis was incorrect. Instead, it *confirmed* that the naproxen hypothesis was a "possible" and "reasonable" explanation for VIGOR's results and that "the reason for the difference between Vioxx and naproxen has not been determined" and was "not clear." JA340, 342, 344. The only remedy it ordered was a letter of correction to those doctors and pharmacists who had heard the particular presentations. JA353.

Nothing in DDMAC's letter would have led a reasonable investor to believe that the naproxen hypothesis was even incorrect, much less suspect that Merck itself *internally* had rejected the hypothesis as the "likely explanation" years earlier.[28] Rather, that investor would have concluded (as financial market participants did) that the naproxen hypothesis was still unproven but viable and that Merck merely had been overzealous in running afoul of FDA's strict marketing regulations.[29]

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[28] Merck asserts that, "[t]o the extent that FDA accused Merck of 'misrepresent[ing] the safety profile for Vioxx,' it would at a minimum suggest the possibility that any opinion expressed by Merck concerning Vioxx's safety profile was not sincerely held." Br. 36-37 n.8. To the contrary, the omission of publicly available alternative scientific explanations for the VIGOR data from the specific marketing presentations made to 100 doctors and 1,300 pharmacists suggests overzealous marketing by a handful of individuals, not a fraud on financial markets.

[29] The point is not, as Merck says, simply that DDMAC's letter "did not specifically accuse Merck of securities fraud." Br. 35 (emphasis omitted). Rather, DDMAC stated affirma-

In addition, because the market had known already for some time that Vioxx might increase the risk of heart attacks, and that the naproxen hypothesis was an unproven theory, DDMAC's letter gave Merck's investors no reason to suspect that Merck had withheld any material information from investors.[30] In an "efficient market," securities analysts, professional investment advisors, and other market professionals evaluate "all publicly available information" about a company. *Basic*, 485 U.S. at 246, 248. By their propagation of that information and their trading patterns, they cause the company's stock price to reflect the totality of that information. *See id.* at 246. It is well-established that a failure to repeat information that is already "well known to the market" is immaterial as a matter of law. *E.g.*, *Longman v. Food Lion, Inc.*, 197 F.3d 675, 684 (4th Cir. 1999); *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1115 (9th Cir. 1989) ("[I]n a fraud on the market case, the defendant's failure to disclose material information may be excused where that information has been made credibly available to the market by other sources."); *accord Basic*, 485 U.S. at 248. Even outside the efficient-market context, the securities laws do not require repetitive disclosure of publicly known information. *See, e.g., Klein v. General Nutrition Cos.*, 186 F.3d 338, 342-43 (3d Cir. 1999).

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tively that the naproxen hypothesis was a possible explanation, though not proven, and that the naproxen hypothesis had a "reasonable" basis. JA340.

[30] That DDMAC's letter contained nothing new to the market is shown by several facts: (1) numerous analysts said so, (2) no analyst downgraded Merck's stock after the letter, and (3) Merck's stock suffered no long-term price drop. *See supra* p. 8.

Those principles contrast sharply with FDA marketing rules. FDA's regulations seek to ensure that each consumer and health care professional *actually receives* full and balanced information concerning a drug's risks. Thus, FDA requires that each promotional item or advertisement, viewed in isolation, presents a "fair balance" of information relating to both effectiveness and risks, even where that information has previously been widely disseminated. *See* 21 C.F.R. §202.1(e)(5)(ii). Communications to patients or health professionals that violate those regulations may thus be deemed "false, lacking in fair balance, or otherwise misleading" within the particularized meaning of FDA's regulations, JA339, but that does not make them Rule 10b-5 violations or even suggestive of a §10(b) violation.

In DDMAC's letter, FDA regulations required that information regarding Vioxx's risks be included in each marketing statement, even though, as an analyst noted, those risks were "likely . . . already common knowledge in the medical community," JA618. For the investment community, which also long had known that the naproxen hypothesis was only a hypothesis and that there was a risk that Vioxx might cause heart attacks, nothing in DDMAC's letter suggested that Merck had withheld any material information from the public.

3. Consumer lawsuits

The handful of tort suits filed by Vioxx users in 2001 who claimed that the drug had injured them did not give Merck's investors a reason to suspect a §10(b) violation. Personal injury lawsuits against a drug manufacturer by users of the drug are unremarkable. Further, because those suits were based solely on VIGOR's results, *JAMA*'s article, and

DDMAC's letter, they offered investors no more information than those sources originally had, and the elements for the claims in those consumer and tort actions bore no similarity to those needed to suggest a §10(b) violation. *See Gavin v. AT&T Corp.*, 464 F.3d 634, 640 (7th Cir. 2006) (recognizing that securities-fraud suits and consumer-fraud suits are not interchangeable).

4. The Harvard Study

As the Third Circuit correctly found, Pet. App. 47a, reporting of the Harvard Study was the earliest possible time at which investors had a reason to question whether Merck had a genuine, reasonable belief in its naproxen hypothesis. That large, independent, publicly available study cast considerable doubt on Merck's repeated assurances that Vioxx was not pro-thrombotic. Merck's immediate and aggressive criticism of the study's design raised questions about Merck's candor in the Vioxx debate. But reasonable investors also might well have continued to rely without negligence on Merck's continuing reassurances that its own internal analyses and studies showed "no statistically significant difference in the risk of heart attacks" between Vioxx and non-Vioxx users. JA166 (¶293).[31]

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[31] Though Merck makes much (Br. 48) of the fact that one of respondents' counsel said his client had not conducted an "investigation," JA994, that statement should not be taken to mean that respondents never considered public information regarding their investments. Where market professionals did not report evidence suggestive of securities fraud at a publicly traded company, it is unreasonable to require more inquiry by a reasonable investor.

B. Respondents Had No Means To Discover The Facts Constituting Merck's Violation

Even if, as Merck contends, respondents had a duty of inquiry prior to November 2001, Merck has failed to establish that "the means of discovery [was] in [respondents'] power." *Wood*, 101 U.S. at 141. For that reason, there was no actual or constructive discovery, and the statute of limitations could not have run.

Merck has never identified any facts available to investors that would have revealed the violation alleged before November 6, 2001. No information accessible to an ordinary investor who inquired at that time demonstrated that the naproxen hypothesis was likely wrong, much less that Merck did not actually believe in it. The means of discovery did not reside in documents to which respondents had access, *see Burke*, 83 U.S. at 401, nor were they available from public records, *see Wood*, 101 U.S. at 139-40. Instead, the facts constituting the violation could be pieced together only from internal data and emails "in the control of the putative defendant, unavailable to the plaintiff." *Kubrick*, 444 U.S. at 122.

In arguing that its investors had a reason to suspect fraud, Merck relies on what it calls "an enormous volume of news stories, academic articles, and analyst reports debating the merits of (and, in many instances, casting doubt on) Merck's position" supporting the naproxen hypothesis.[32] Br. 34. But expressions of "doubt" about an opinion's substantive

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[32] The stories, articles, and reports also were available, of course, to the market – which as a whole did not discover Merck's fraud until much later. JA198 (¶337) (analyst's comment in November 2004 that the newly disclosed emails showed "the situation might not be as innocent as we thought").

correctness do not suggest fraud, much less enable a reasonable investor to discover Merck's violation of §10(b). In addition, even FDA – with its scientific expertise and access to (some of) Merck's confidential data – accepted the legitimacy of the naproxen hypothesis and, at least as of April 2002, considered the "significance" of VIGOR's results to be "unknown." JA140 (¶251). And doctors continued to write billions of dollars' worth of Vioxx prescriptions. With the true facts tightly under its corporate control, Merck cannot carry its burden to establish, as a matter of law, that investors should have discovered facts constituting a violation prior to November 2001.[33]

* * *

The Third Circuit thus correctly held that, as of two years prior to the first complaint's filing, "market analysts, scientists, the press, and even the FDA agreed that the naproxen hypothesis was plausible, at the very least. None suggested that Merck believed otherwise. . . . [I]n April 2002, the FDA approved a labeling change for Vioxx which stated that '[t]he significance of the cardiovascular findings [from the VIGOR study] is unknown.'" Pet. App. 46a (first and second alteration added). Respondents therefore were not on inquiry notice that Merck's statements of belief were false, and thus they could

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[33] Additionally, Merck continued to make independently actionable false statements after November 2001. Each new false statement constituted a new "untrue statement of a material fact or . . . omi[ssion] [of] . . . a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. §240.10b-5(b). Because this action was filed within two years of those statements, the statute cannot have run with respect to those violations.

not have had a duty to inquire as to the existence of §10(b) violations.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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REPLY BRIEF

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In the Supreme Court of the United States

MERCK & CO., INC., ET AL., PETITIONERS

v.

RICHARD REYNOLDS, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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SUPPLEMENT TO CORPORATE DISCLOSURE STATEMENT

Since the filing of petitioners' opening brief, petitioner Merck & Co., Inc., has completed its merger with Schering-Plough Corporation. The combined entity now operates under the name of Merck & Co., Inc.; the entity formerly known as Merck & Co., Inc., is now known as Merck Sharpe & Dohme Corp., a wholly owned subsidiary.

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In the Supreme Court of the United States

No. 08-905

MERCK & CO., INC., ET AL., PETITIONERS

v.

RICHARD REYNOLDS, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

The Court granted review in this case on the question whether, in order to be on inquiry notice of his claim, a securities-fraud plaintiff must possess information that the defendant acted with scienter—a question on which the circuits are in clear conflict. As explained in petitioners' opening brief, the answer to that question is no. To be on inquiry notice, a plaintiff need not possess information specifically bearing on every element of the underlying violation. Under any standard, moreover, respondents were on inquiry notice of their claim more than two years before the initial complaint was filed, because they possessed considerable information suggesting the possibility that petitioners had committed securities fraud—including information specifically suggesting that petitioners acted with scienter.

Confronted with the question on which this Court granted review, respondents simply ignore it. Having urged the court of appeals to hold that a securities-fraud plaintiff must possess information specifically relating to scienter in order to be on inquiry notice, respondents skirt the question presented and instead present two different questions of their own, neither of which even mentions inquiry notice. And they essentially ask the Court to affirm on an alternative ground: *viz.*, that, even assuming respondents were on inquiry notice, petitioners have not shown that respondents possessed the means of completing an investigation and obtaining any necessary remaining information concerning the alleged violation. There is no valid justification for such a requirement. If adopted, it would threaten to eviscerate the limitations defense in private securities-fraud actions. And it would be particularly inequitable where, as here, the plaintiffs conducted no investigation at all, but rather waited until their claim was sufficiently lucrative before filing suit.

More broadly, however, the Court should not countenance respondents' refusal to join issue. In order to dispose of this case, the Court need only address the question presented, and hold that a securities-fraud plaintiff may be on inquiry notice without possessing information specifically relating to scienter.

A. Respondents Were On Inquiry Notice Of Their Securities-Fraud Claim More Than Two Years Before The Initial Complaint Was Filed

1. To Be On Inquiry Notice, A Plaintiff Need Not Possess Information Specifically Relating To Scienter

a. At the outset, respondents do not seriously dispute (Br. 25-27) that the limitations period in Section 1658(b) is triggered by constructive, as well as actual,

discovery of the "facts constituting the violation." Nor could they, because it is well established that, when a statute of limitations incorporates the discovery rule, the limitations period begins to run from the date of either actual or constructive discovery. See U.S. Br. 15-16.

Citing the language of Section 1658(b), however, respondents suggest (Br. 16-17, 27, 28, 32) that, in applying that provision, a court should simply determine when a hypothetical plaintiff should have discovered the facts constituting the violation. Although the statutory language is, as always, the starting point of the analysis, that language cannot meaningfully be understood without reference to the considerable body of preexisting common law concerning the discovery rule—and, specifically, concerning the doctrine of inquiry notice. This Court has long recognized the applicability of that doctrine to fraud claims more generally. See, *e.g.*, *Burke* v. *Smith*, 83 U.S. (16 Wall.) 390, 401 (1873). And by the time Section 1658(b) was enacted, all but one of the regional circuits had done the same for securities-fraud claims specifically (and the remaining circuit, the Ninth, subsequently followed suit). See U.S. Br. 16 n.3 (citing cases). It is therefore clear that, in enacting Section 1658(b), Congress understood that the principle of inquiry notice was integral to the discovery rule that it was codifying.

b. Facing a solid wall of authority supporting the proposition that the discovery rule in Section 1658(b) incorporates the doctrine of inquiry notice, respondents acknowledge (Br. 28) that inquiry notice may be relevant to the analysis, if only "occasionally." But respondents then proceed to define inquiry notice in an untenably narrow manner. Specifically, respondents contend that, to be on inquiry notice, a plaintiff must possess not only "information suggesting possible fraud," but also "the

means of * * * obtaining" any necessary remaining information concerning the alleged violation. *Ibid.*

Properly understood, however, "inquiry notice" refers only to the first component of respondents' definition. Both before and after the enactment of Section 1658(b), the prevailing view in the lower courts was that, as the name suggests, a plaintiff is on inquiry notice when he possesses information sufficient to trigger a duty to inquire further: *i.e.*, when there is enough information in the plaintiff's possession, or in the public domain, to cause a reasonable investor to suspect the possibility that the defendant has engaged in securities fraud. See Pet. Br. 21 (citing cases).[1] That is how respondents' amici, including the government, understand the concept of inquiry notice. See, *e.g.*, U.S. Br. 16-17. And at earlier stages of this case, that is how *respondents* understood it as well. See Br. in Opp. 15; J.A. 996-997 (statement of Melvyn Weiss).

c. Respondents seemingly recognize that, for purposes of establishing when a plaintiff is on inquiry notice, a court must first establish the point at which the plaintiff "obtain[s] information suggesting possible fraud." Br. 28. Respondents avoid taking a position, however, on *how much* information a securities-fraud plaintiff must possess in order to be on inquiry notice—and, specifically, on whether a plaintiff must possess information that the defendant acted with scienter.[2]

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[1] Respondents concede (Br. 28 n.11) that information in the public domain "usually provides the predicate for asking whether an investor should * * * have inquired further."

[2] The closest that respondents come is the coy assertion (made without reference to inquiry notice) that "actual or constructive knowledge of scienter is essential to trigger the running of the statute." Br. 43.

Instead, respondents contend (Br. 19, 43), as they did at the certiorari stage, that the court of appeals did not hold that a plaintiff must possess information specifically relating to scienter in order to be on inquiry notice. To the extent the Court has not already rejected that contention in granting review, it is refuted not only by the court of appeals' opinion, see Pet. App. 33a, but also by a subsequent opinion in which the court of appeals reaffirmed that "inquiry notice, in securities fraud suits, requires storm warnings indicating that defendants acted with scienter," *Alaska Elec. Pension Fund* v. *Pharmacia Corp.*, 554 F.3d 342, 348 (3d Cir. 2009), petition for cert. pending, No. 08-1315 (filed Apr. 22, 2009). Several of respondents' amici, including the government, agree that the court of appeals so held. See, *e.g.*, U.S. Br. 27. And it is ironic that respondents are now arguing that the court of appeals did not adopt that holding when *they* encouraged the court to adopt it in the first place. See Resp. C.A. Br. 31.

For the reasons stated in petitioners' opening brief (at 19-28), there is no valid justification for the court of appeals' rule. In order to suspect that the defendant has engaged in wrongdoing, a plaintiff need not possess information specifically bearing on each and every element of the underlying violation. This Court has recognized that principle implicitly in the specific context of inquiry notice, see *TRW Inc.* v. *Andrews*, 534 U.S. 19, 30 (2001), and explicitly in the broader context of the discovery rule, see *Rotella* v. *Wood*, 528 U.S. 549, 556-561 (2000); *Klehr* v. *A.O. Smith Corp.*, 521 U.S. 179, 186-191 (1997); *United States* v. *Kubrick*, 444 U.S. 111, 118-125 (1979). From the innumerable cases applying the discovery rule to ordinary fraud claims, moreover, respondents fail to identify a single case adopting the rule that a plaintiff

cannot be on inquiry notice until he possesses information specifically relating to scienter.

While the government at least engages the question presented, it too does not defend the court of appeals' bright-line rule, recognizing that there are cases in which "information giving rise to a suspicion of falsehood will itself give rise to a suspicion of fraud." Br. 29. This Court should therefore hold that the court of appeals erred by requiring a securities-fraud plaintiff to possess information specifically relating to scienter in order to be on inquiry notice.[3]

2. *Under Any Standard, Respondents Were On Inquiry Notice More Than Two Years Before The Initial Complaint Was Filed*

Although respondents do not take a definite position on the question presented, they nevertheless contend (Br. 46-53) that the court of appeals correctly held that they were not on inquiry notice of their claim more than two years before the initial complaint was filed. By that date, however, there was considerable information in the public domain suggesting the possibility that petitioners had engaged in securities fraud—including information specifically suggesting that petitioners had made misstatements with scienter. Respondents thus were on inquiry notice under any standard.

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[3] The government renews its contention (Br. 13) that, for discovery to occur under Section 1658(b), a plaintiff must possess sufficient information to file a complaint that would survive a motion to dismiss under the Private Securities Litigation Reform Act of 1995 (PSLRA). That contention lacks merit for the reasons stated in petitioners' opening brief (at 28-33). Unlike the government, respondents do not attempt to connect the running of the statute of limitations to the applicable pleading standards; indeed, respondents do not even mention the PSLRA.

a. Respondents assert (Br. 46-47) that the "gravamen" of their securities-fraud claim is that Merck engaged in misrepresentations when it expressed its *opinion* that the "likely" explanation for the disparity in cardiovascular events reported in the VIGOR study was that naproxen prevented blood clots. As a threshold matter, respondents' recent recharacterization of the alleged misstatements as statements of opinion does not materially affect the analysis. For a statement of opinion to be actionable, a securities-fraud plaintiff must show both that the statement lacked a reasonable basis in fact and that the expressed opinion was not genuinely held. See *Virginia Bankshares, Inc.* v. *Sandberg*, 501 U.S. 1083, 1091-1096 (1991). Those requirements roughly correspond to the requirements of falsity and scienter for statements of fact. Assuming, *arguendo*, that respondents correctly characterize the alleged misstatements as statements of opinion, the critical question is therefore whether respondents were required to possess information specifically suggesting that Merck's opinion was not genuinely held, as the court of appeals concluded—and, even assuming they were, whether they did in fact possess such information.[4]

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[4] Respondents' recharacterization of the alleged misstatements as statements of opinion, moreover, casts serious doubt on whether those misstatements would even be actionable. Where, as here, the statements at issue merely involve an expressed belief in a *medical hypothesis* (and that belief was reasonably based on data available at the time), the statements do not lack a reasonable basis in fact and are therefore not actionable. See, *e.g.*, *Oran* v. *Stafford*, 226 F.3d 275, 282-283 (3d Cir. 2000). The government hints that it agrees. See Br. 31 (stating that "[a]n issuer of securities * * * does not engage in fraud or deceit by failing to give equal attention to a competing theory in all its public utterances simply because the issuer's explanation ultimately turns out to be wrong").

b. Respondents' efforts to minimize the significance of the three primary sources of information in the public domain—the warning letter from the Food and Drug Administration (FDA), the pending lawsuits concerning the safety of Vioxx, and the articles and analyst reports on the same subject—are unavailing.

As to the FDA warning letter, respondents contend that the letter "primarily focused" on "certain marketing statements made by a Merck consultant and Merck personnel manning a convention sales booth" and alleged only that those statements were incomplete. Br. 7, 49. That contention substantially understates the significance of the warning letter for purposes of the inquiry-notice analysis.[5] In that letter, FDA also focused on a May 22, 2001, press release in which Merck referred to the "favorable cardiovascular safety profile of Vioxx," see J.A. 339, 351—a statement that is one of the alleged misstatements most prominently featured in respondents' complaint, see J.A. 113-114. Citing the press release, FDA charged that, while the naproxen hypothesis was a "*possible*" explanation for the cardiovascular disparity, Merck had "engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the [VIGOR] study, and thus, *misrepresents* the safety profile for Vioxx." J.A. 340 (emphases added). And specifically referring to the press release, FDA further charged—in statements highlighted in respondents' complaint, see J.A. 122-123—that Merck's claim that Vioxx had a "fa-

[5] Respondents suggest (Br. 8) that FDA warning letters are routine in the pharmaceutical industry. In their complaint, however, respondents contended that FDA warnings were "sent only to address serious circumstances." J.A. 71.

vorable cardiovascular safety profile" was "simply incomprehensible," and that the implication that Vioxx was safer than other anti-inflammatory medicines was "misleading." J.A. 351.

In the warning letter, therefore, FDA accused Merck of *deliberate* wrongdoing in connection with those representations. In light of FDA's allegations, respondents plainly possessed information casting doubt on the genuineness of Merck's belief in its opinion, as reflected in the press release and in other statements, that the naproxen hypothesis was the likely explanation for the cardiovascular disparity in the VIGOR study. And respondents cannot credibly dispute that understanding of the FDA warning letter, because, in prior versions of their complaint, they themselves cited it as evidence of scienter. See J.A. 265, 266. Respondents simply ignore their earlier characterization—and therefore fail to offer any reason why they should not be held to it.

As to the pending Vioxx-related lawsuits, respondents contend that those lawsuits were "personal-injury suits" alleging that "Merck had failed directly to warn Vioxx users on an individual basis of the drug's potential risks." Br. 8-9. Respondents understate the significance of those lawsuits as well. The suits alleged that Merck had, *inter alia*, "*purposefully* downplayed and/or understated the serious nature of the risks associated with Vioxx." J.A. 893 (emphasis added). Moreover, the suits included not just negligence-based failure-to-warn claims, but also consumer-fraud claims, which, like securities-fraud claims, are premised on the making of misstatements or omissions with scienter. See J.A. 893-897, 943-947. Even if they are based on different legal theories, moreover, the existence of other lawsuits based on the same underlying *allegations* is powerful evidence that a securities-fraud plaintiff was on inquiry notice.

See, *e.g.*, *Masters* v. *GlaxoSmithKline*, 271 Fed. Appx. 46, 49 (2d Cir. 2008).[6]

As to the articles and analyst reports, respondents emphasize (Br. 48) that those articles recognized that the naproxen hypothesis was a *possible* explanation for the cardiovascular disparity. Many of those articles, however, also cast substantial doubt on the validity of the naproxen hypothesis—and therefore on the validity of Merck's belief that the hypothesis was the *likely* explanation for the disparity. For example, the August 22, 2001, article in the Journal of the American Medical Association (JAMA), while recognizing that "[t]he results of the VIGOR study can be explained by * * * an [anti-clotting] effect from naproxen," J.A. 326, ultimately concluded that "[t]he available data raise a cautionary flag about the risk of cardiovascular events with COX-2 inhibitors." J.A. 332. Those articles, when considered together with the FDA warning letter and the pending lawsuits, were sufficient to put respondents on inquiry notice under any standard.[7]

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[6] Respondents suggest that "[p]ersonal injury lawsuits against a drug manufacturer by users of the drug are unremarkable." Br. 52. It cannot be said, however, that the filing of *more than two hundred lawsuits* concerning the same drug is unremarkable. Yet that was the state of affairs concerning Vioxx when the initial securities-fraud complaint was filed.

[7] In an amicus brief, two doctors contend that, "[a]s of November 6, 2001, a reasonable medical professional would have concluded that the naproxen hypothesis was likely correct." Krumholz Br. 22. That contention is suspect. Both doctors acknowledge that they have worked as experts for plaintiffs in Vioxx-related product-liability litigation against Merck, see *id.* at 3, and one of the doctors testified in that litigation that he believed the naproxen hypothesis to be "a stretch" and that he "never found it plausible," see Tr. at 2620-2621,

c. Notably, it can no longer be disputed that respondents were on inquiry notice under the government's proposed standard, pursuant to which a plaintiff need not possess information specifically relating to scienter if the alleged misstatements involved information that is within the "knowledge" or "control" of the defendant. Br. 29-30.[8] Respondents repeatedly concede—as they must, given their characterization of the alleged misstatements as statements of opinion—that those statements involved information "under Merck's exclusive control." Br. 21; see Br. 32, 54, 55. For that reason, the government's tepid suggestion (Br. 30-31) that respondents were not on inquiry notice cannot be squared with its proposed standard. Under that or any other standard, respondents were on inquiry notice more than two years before the initial complaint was filed, and the court of appeals' contrary conclusion was erroneous.[9]

Hermans v. *Merck & Co.*, No. ATL-L-5520-05MT (N.J. Super. Ct. Feb. 5, 2007) (testimony of Dr. Krumholz).

[8] In a delphic footnote, the government suggests (Br. 30 n.8) that, under its proposed standard, a plaintiff may still need to possess information specifically relating to scienter in some circumstances where the alleged misstatements involved information that is within the defendant's control. The government, however, does not elaborate on that suggestion.

[9] Respondents contend that, even if they would otherwise have been on inquiry notice based on information in the public domain, any notice was "extinguished" by "reassurances" given by Merck. Br. 48-49. Far from providing "reassurances" in response to any investigation by respondents, however, Merck merely made subsequent statements that were similar in content to its prior statements. Respondents' contention would permit a plaintiff effectively to extend the limitations period by asserting a "continuing violation" from the date of the first alleged misstatement in contravention of the principle that each alleged misstatement constitutes a separate

3. *Respondents Offer No Alternative Explanation For When They Were On Inquiry Notice*

Although respondents contend that the court of appeals correctly held that they were not on inquiry notice of their claim more than two years before the initial complaint was filed, they conspicuously fail to take a position on when, if ever, they were on inquiry notice. Neither of the potential alternative dates is plausible, and the problems with those dates reflect broader difficulties with respondents' approach.

a. The court of appeals held that respondents were not on inquiry notice until October 30, 2003, when the Wall Street Journal reported on a study by the Brigham and Women's Hospital in Boston suggesting that the available data indicated that patients taking Vioxx faced a greater risk of cardiovascular events. See Pet. App. 18a, 47a. Respondents, however, stop short of affirmatively arguing that they were on inquiry notice as of that date, see Br. 53, and for good reason. For purposes of the inquiry-notice analysis, the Wall Street Journal ar-

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"violation" for purposes of Section 1658(b). See, *e.g.*, *In re Exxon Mobil Corp. Sec. Litig.*, 500 F.3d 189, 200 (3d Cir. 2007).

Inconsistently with the foregoing contention, respondents also contend that "Merck continued to make independently actionable false statements after November 2001," which would constitute separate violations that are not time barred even if respondents were on inquiry notice as of that date. Br. 55 n.33. As a preliminary matter, the operative version of respondents' complaint primarily focuses on a series of statements made *before* November 2001. See J.A. 82-127. In any event, any alleged misstatements made after the inquiry-notice date would not be actionable, because plaintiffs could not reasonably rely on such statements when they had reason to suspect that similar prior statements were false. See, *e.g.*, *Alaska Electrical Pension Fund*, 554 F.3d at 351; *Shah* v. *Meeker*, 435 F.3d 244, 252 (2d Cir. 2006).

ticle added little, if anything, to the information already in the public domain. Like the study reported in the 2001 JAMA article, the Brigham and Women's study was a retrospective analysis of publicly available data, and, when the results of that study were published, they in fact showed no statistically significant increase in the risk of cardiovascular events for patients taking Vioxx when compared to patients taking other types of anti-inflammatory medicines (or none at all). See Daniel H. Solomon et al., *Relationship Between Selective Cyclooxygenase-2 Inhibitors and Acute Myocardial Infarction in Older Adults*, 109 Circulation 2068, 2071 (2004). Tellingly, the Wall Street Journal article scarcely merited a mention in prior versions of the complaint: unlike the FDA warning letter and the pending lawsuits, it was not cited at all in the section of the complaint entitled "Additional Scienter Allegations," see J.A. 265-269, and, in the initial complaint, it was described as merely "*further* acknowledg[ing] and report[ing]" "[t]he seriousness of th[e] risks" associated with Vioxx, C.A. App. 1221 (emphasis added).

Respondents identify no other information that came into the plaintiffs' possession after November 6, 2001, that triggered the filing of the initial securities-fraud complaint on November 6, 2003. The inescapable conclusion is that the plaintiffs brought suit on that date not because they had only recently been placed on inquiry notice, but rather because a securities fraud action had only recently become worth their while—due to a considerable drop in Merck's stock price attributable not to the Wall Street Journal article, but rather to a disappointing earnings report issued shortly earlier. See J.A. 999 (statement of Melvyn Weiss).

b. Respondents repeatedly suggest that it was not until the publication of a subsequent Wall Street Journal

article on November 1, 2004, that they learned of "Merck's longstanding belief that Vioxx caused adverse cardiovascular events." Br. 2; see Br. 10, 54 n.32. As a logical matter, however, it cannot be that respondents were not on inquiry notice until that date. That would imply that the plaintiffs in this case brought suit nearly a year before a reasonable investor would have even *suspected the possibility* that petitioners had engaged in securities fraud—and therefore before the limitations period had even *begun* to run.

Respondents' suggestion also illustrates two broader conceptual problems with their approach. First, if the limitations period began to run only as of November 1, 2004, the plaintiffs would not have needed to file the first securities-fraud complaint until two years later—or November 1, 2006. That approach would render the statute of limitations effectively irrelevant in this case—as, presumably, in many if not most others—leaving the statute of repose as the only source of protection for defendants. Such a result would contravene not only Congress's evident intention that the limitations period have independent meaning, see S. Rep. No. 146, 107th Cong., 2d Sess. 8-10 (2002), but also the broader principle that statutes of limitations, no less than statutes of repose, are designed to afford protection against stale claims, even if they operate in different ways, see 1 Calvin W. Corman, *Limitation of Actions* § 1.1, at 4-5 (1991).[10]

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[10] Contrary to respondents' repeated suggestions (Br. 17, 33), in his dissent in *Lampf, Pleva, Lipkind, Prupis & Petigrow* v. *Gilbertson*, 501 U.S. 350 (1991), Justice Kennedy merely expressed concern that, because it was not subject to any equitable exception, the Court's three-year *repose* period would terminate the claims of "injured investors who by no conceivable standard of fairness or practicality c[ould] be expected to file suit" in a timely manner. *Id.*

Second, if the limitations period began to run only as of November 1, 2004, it would seemingly conflate inquiry notice with actual discovery in this case, because respondents concede that *all* of the relevant information concerning the alleged violation was in the public domain by that date. See Br. 2; J.A. 197. Indeed, respondents appear to suggest that, by virtue of the "efficient market" hypothesis, in *any* case involving alleged fraud on the market by a publicly traded company, a plaintiff cannot be said to have discovered the underlying violation until all of the relevant information becomes publicly available. See Br. 51, 53 n.31. Insofar as that suggestion would effectively require actual discovery, however, it cannot be reconciled with respondents' implicit concession (Br. 25-27) that *constructive* discovery of the "facts constituting the violation" also triggers the running of the limitations period in Section 1658(b). In sum, respondents cannot justify the selection of any later date as the date of inquiry notice—and the court of appeals' holding that respondents were not on inquiry notice more than two years before the initial complaint was filed therefore cannot be sustained.

B. Under Section 1658(b), Respondents' Claim Is Untimely

To dispose of this case, the Court need only determine that the court of appeals erred by holding that a securities-fraud plaintiff is not on inquiry notice until he possesses information that the defendant acted with scienter. Should the Court reach the broader issue of

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at 377. Justice Kennedy agreed that a one-year *limitations* period was appropriate, *id.* at 374—and, of course, Congress subsequently lengthened both periods.

how the date on which a plaintiff is on inquiry notice affects the running of the statute of limitations, however, it should hold that, at least where, as here, the plaintiff fails to conduct a reasonably diligent investigation, the limitations period begins to run from the date of inquiry notice.

1. To begin with, there is strong support for the proposition that the date on which a plaintiff is on inquiry notice should *always* trigger the running of the limitations period. See Pet. Br. 39-43. Such a categorical approach would be the easiest of the potential approaches to administer, because there will often be a particular event that unambiguously places the plaintiff on inquiry notice. And it is consistent with the text of Section 1658(b), because the phrase "facts constituting the violation" in Section 1658(b) is properly understood not to encompass the fact of scienter in the first place.

Respondents fail to offer a valid response to the contention that the phrase "facts constituting the violation" in Section 1658(b) reaches only the core nucleus of facts concerning the defendant's *conduct*, separate and apart from the fact of the defendant's *state of mind*. They do not dispute that, under the discovery rule, the default principle is that "[a]ccrual of the plaintiff's cause of action does not depend on his or her acquisition of information in proof of scienter." 2 Corman § 11.5.7, at 202. Nor do they dispute that this Court recently drew the *identical* distinction in discussing the pleading rules specifically applicable to securities-fraud claims, see *Tellabs Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007), or that the Federal Rules of Civil Procedure draw a similar distinction in setting the pleading rule for fraud claims more generally, see Fed. R. Civ. P. 9(b).

Instead, respondents merely contend (Br. 23-25) that scienter is an element of the cause of action under Sec-

tion 10(b) and that plaintiffs have long been required to allege scienter in pleading a claim for fraud. Both of those contentions are correct, but beside the point. Section 1658(b) does not require the plaintiff to discover the "facts constituting all of the elements of the cause of action" (or even the "facts constituting the cause of action," as the Field Code required). Instead, it merely requires the plaintiff to discover the "facts constituting the *violation*," and that phrase is readily understood to reach only the facts relevant to the defendant's *conduct*. The text of Section 1658(b) therefore supports a categorical approach, under which a plaintiff need not possess information specifically relating to scienter in order to trigger the limitations period.

2. In this case, however, the Court need not definitively resolve whether the date on which a plaintiff is on inquiry notice should *always* trigger the running of the limitations period. Instead, should the Court reach the issue, it need only hold, as the Second and Third Circuits have done, that, where a plaintiff is on inquiry notice but fails actually to conduct a reasonably diligent investigation, the limitations period begins to run from that date.

a. Respondents (Br. 38) primarily contend that the Second and Third Circuits' approach would be inconsistent with the language of Section 1658(b). Respondents fundamentally err, however, because they operate as if the discovery rule codified in Section 1658(b) should be interpreted in a vacuum, without reference to the considerable body of common law concerning the discovery rule that preceded its enactment. That body of common law decisively supports the Second and Third Circuits' approach, because it makes clear that consideration of a plaintiff's actual investigation is embedded in the application of the discovery rule. See U.S. Br. at 28, *United States* v. *Beggerly*, 524 U.S. 38 (1998) (No. 97-731) (not-

ing that the discovery rule "incorporates equitable considerations").

i. The discovery rule originated in equity, and "[o]ne of the familiar maxims of equity is that equity aids those who have been vigilant or diligent, not those who sleep or slumber on their rights." 27A Am. Jur. 2d *Equity* § 93, at 631 (2008). Accordingly, as respondents freely concede, this Court has repeatedly stated that "a plaintiff must be diligent (or at least free of negligence or laches) to take advantage of the discovery rule as a matter of equity." Br. 39. In *Bailey* v. *Glover*, 88 U.S. (21 Wall.) 342 (1875), the Court explained that the discovery rule was applicable only where "there has been no negligence or laches on the part of a plaintiff in coming to the knowledge of the fraud which is the foundation of the suit." *Id.* at 349. In *United States* v. *Diamond Coal & Coke Co.*, 255 U.S. 323 (1921), the Court reasoned that, where there has been "laches resulting from failure to make inquiry," such laches would "take the case out of the equitable principle" that is the discovery rule, because laches is "the fundamental principle upon which the equitable doctrine * * * rest[s]." *Id.* at 333, 334. And in *Holmberg* v. *Armbrecht*, 327 U.S. 392 (1946), the Court noted that a plaintiff could not invoke the discovery rule where there was "any fault or want of diligence or care on his part." *Id.* at 397 (citation omitted). Respondents' sole basis for distinguishing those cases is that they "appl[ied] nonstatutory equitable doctrines to differently worded statutes." Br. 38. The "equitable doctrine" those cases apply, however, is the same one codified in Section 1658(b)—and those cases establish the

principle that a plaintiff who sleeps on his rights is not entitled to the benefit of the discovery rule.[11]

Respondents cite (Br. 35-41) numerous of this Court's cases, but none is to the contrary. In three of those cases, the Court actually *reaffirmed* the principle that the plaintiff must exercise "reasonable" or "due" diligence to invoke the discovery rule (or avoid laches); at most, the Court also noted, in concluding that the plaintiff had made no effort to investigate, that he could readily have discovered the fraud if he had tried. See *Foster* v. *Mansfield, Coldwater & Lake Mich. R.R. Co.*, 146 U.S. 88, 99-100 (1892); *Kirby* v. *Lake Shore & Mich. S. R.R. Co.*, 120 U.S. 130, 136-137 (1887); *Wood* v. *Carpenter*, 101 U.S. 135, 139-140, 141, 143 (1879). In a fourth, the Court similarly explained, after holding that the plaintiffs' claim was meritless, that the claim would have been time-barred in any event because the plaintiffs were on inquiry notice well before filing suit (and had made no effort to investigate). See *Burke*, 83 U.S. (16 Wall.) at 401. And in the other two, the Court did not address any issue concerning the discovery rule, but rather the entirely distinct issue of when an individual qualified as a bona fide purchaser of property. See *Indiana & Ill. Cent. Ry. Co.* v. *Sprague*, 103 U.S. 756, 762 (1881); *Oliver* v. *Piatt*, 44 U.S. (3 How.) 333, 409-410 (1845).

ii. Among this Court's more recent decisions, *Klehr* conclusively supports the proposition that a plaintiff must act with reasonable diligence in order to receive the

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[11] The government entirely ignores those cases, instead asserting in passing that "[l]aches within the term of the statute of limitations is no defense at law." Br. 21 (citation omitted). That is true in the case of a traditional injury-based limitations period, but, as the foregoing cases illustrate, not in the case of an equitable discovery-based period.

benefits of the discovery rule. There, the Court held that a plaintiff must act with reasonable diligence to invoke the doctrine of fraudulent concealment. See 521 U.S. at 193-196.[12] Although *Klehr* involved the Racketeer Influenced and Corrupt Organizations Act (RICO), its reasoning is equally applicable here, because private securities-fraud actions, like civil RICO actions, are designed not only to "compensate victims," but also to "encourage those victims themselves diligently to investigate and thereby to uncover unlawful activity." *Id.* at 195.[13] Indeed, *Klehr*'s reasoning applies *a fortiori* here in an important respect: respondents do not invoke the "fraudulent concealment" doctrine (by alleging that petitioners engaged in any affirmative act of concealment), but instead contend only that they would have been unable to discover any additional information if they had con-

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[12] Respondents suggest (Br. 39) that *Klehr* does not support petitioners' position because the Court understood that a plaintiff could exercise "reasonable diligence" by doing nothing where the plaintiff would have been unable to discover the relevant facts. That suggestion makes no sense. If respondents are correct, the Court would not have needed to address the interplay between a plaintiff's diligence and the doctrine of fraudulent concealment: where a defendant engaged in fraudulent concealment, the plaintiff would by definition be reasonably diligent.

[13] In *TRW*, the Court, in refusing to read a discovery rule into the Fair Credit Reporting Act, reasoned that a discovery rule would render an express statutory exception for cases involving misrepresentations superfluous *in cases involving fraudulent concealment*. See 534 U.S. at 31. To the extent the Court's opinion is read more broadly to suggest that a plaintiff need not act with reasonable diligence in order to invoke the doctrine of fraudulent concealment, that suggestion cannot be reconciled with the more extended discussion in *Klehr*.

ducted an investigation (because that information was "under Merck's exclusive control"). Br. 21.[14]

b. Contrary to respondents' contention (Br. 40-41), when Congress enacted Section 1658(b), the principle that the limitations period begins to run from the date of inquiry notice where the plaintiff fails to conduct a reasonably diligent investigation was already well established in the Second Circuit—the Nation's most experienced circuit in dealing with securities-fraud claims. See, *e.g.*, *Dodds* v. *Cigna Sec., Inc.*, 12 F.3d 346, 350 (2d Cir. 1993) (noting that, "when the circumstances would suggest to an investor of ordinary intelligence the probability that she has been defrauded, a duty of inquiry arises, and knowledge will be imputed to the investor *who does not make such an inquiry*") (emphasis added), cert. denied, 511 U.S. 1019 (1994).[15] In the legislative history, moreover, several Senators cited that principle with approval, specifically quoting the foregoing language from *Dodds*. See S. Rep. No. 146, *supra*, at 29 (additional views of eight Senators).[16] Because Section

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[14] See, *e.g.*, *Benak* v. *Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 401 (3d Cir. 2006) (noting that "[p]laintiffs cannot, *post hoc*, excuse a failure to inquire by demonstrating the difficulty they would have had attaining relevant information"); cf. *Wolin* v. *Smith Barney Inc.*, 83 F.3d 847, 852 (7th Cir. 1996) (suggesting, before *Klehr*, that diligence was required where a fraud was "self-concealing," even if it was not required where the fraud was affirmatively concealed).

[15] District courts in the Second Circuit also routinely applied that principle. See, *e.g.*, *Addeo* v. *Braver*, 956 F. Supp. 443, 449 (S.D.N.Y. 1997) (Sotomayor, J.).

[16] Respondents contend that the views of those Senators are unreliable because they "voted *against* § 1658(b)." Br. 46. In committee, seven of the eight Senators did support an unsuccessful amendment that would have restored the preexisting one-year limitations period, see S. Rep. No. 146, *supra*, at 22—although all eight ultimately

1658(b) merely altered the duration of the limitations period, there is no reason to believe that Congress intended to abrogate the Second Circuit's approach, and good reason to believe that Congress intended to sanction it.[17]

In sum, the Second and Third Circuits' approach can readily be reconciled with the language of Section 1658(b) and is the most consistent with the common-law backdrop against which Section 1658(b) was enacted. Should the Court reach the issue, therefore, it should adopt that approach here. And, under that approach, because respondents again concede (Br. 53 n.31) that they failed to undertake *any* further investigation in the wake of the events that placed them on inquiry notice, their claim is untimely.

3. The government contends (Br. 16-18) that, when a securities-fraud plaintiff is on inquiry notice of his claim, the plaintiff should be entitled to the additional period of time that it would take a hypothetical plaintiff to complete an investigation, regardless whether he actually conducted an investigation himself. For their part, res-

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voted for Section 1658(b) on the Senate floor, see 148 Cong. Rec. 12,508 (2002). More to the point, however, petitioners are relying on the views of those Senators solely concerning the *trigger* for the limitations period—an issue as to which there was no apparent disagreement.

[17] The government contends (Br. 18-19, 22) that, in interpreting Section 1658(b), the Court should look to Section 13 of the Securities Act of 1933, 15 U.S.C. 77m. Courts applying Section 13, however, have taken a similar approach to that of the Second and Third Circuits under Section 1658(b), first considering whether the plaintiff was on inquiry notice and then whether the plaintiff actually conducted a reasonably diligent investigation. See, *e.g.*, *Cook* v. *Avien, Inc.*, 573 F.2d 685, 696, 698 (1st Cir. 1978).

pondents contend (Br. 30-32) that, when a plaintiff is on inquiry notice, the limitations period begins to run only if the plaintiff possesses the "means" of completing an investigation, again regardless of whether he actually conducted an investigation himself.[18] Whatever the differences between respondents' and the government's proposed "hypothetical plaintiff" approaches, those approaches should be rejected for three principal reasons.

a. To begin with, any "hypothetical plaintiff" approach would by definition give a plaintiff the benefit of the additional time it would take to complete an investigation even if the plaintiff did not attempt to conduct one himself—and would therefore effectively excuse an "ostrich" plaintiff's failure to do so. The government contends (Br. 23) that even an "ostrich" plaintiff will eventually have an incentive to investigate, because he will need to acquire facts sufficient to file suit. Under the government's approach, however, a plaintiff need not take any action until the point at which a hypothetical plaintiff would be able to file a complaint *sufficient to survive a motion to dismiss*—and then will have an additional *two years* simply to draft his complaint and file it. That approach would therefore permit the very abuse this case illustrates, by allowing a plaintiff who is already on inquiry notice to lie in the weeds until a company's stock price drops sufficiently and then pounce when the

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[18] Under respondents' approach, it is unclear whether, when a plaintiff does possess the means of completing an investigation, the limitations period would begin to run from the date of inquiry notice or the date on which a hypothetical investigation would have been completed.

value of the claim makes filing suit too tempting to resist.[18]

Conversely, an approach that creates incentives for plaintiffs to conduct a prompt investigation at the point of inquiry notice would impose minimal burdens on plaintiffs, because a plaintiff need only show that he made *reasonable* efforts to investigate—and, where those efforts are unsuccessful, will be entitled to additional time until the remaining information concerning the violation becomes available. While some of respondents' amici suggest that such a requirement will still impose excessive burdens on "retired school teacher[s] in Boca Raton," CtW Br. 24, others correctly recognize "the reality of class action securities litigation": *viz.*, that the lead plaintiffs are usually large institutional investors that possess ample resources to conduct investigations themselves. Faculty Br. 32. And to the extent they do not, there are plenty of plaintiffs' lawyers eager to conduct investigations on their behalf, in return for a healthy share of any ultimate verdict (or, more likely, settlement). See SIFMA Br. 13-18; DRI Br. 25-28.

b. A "hypothetical plaintiff" approach would also leave no meaningful role for the principle of inquiry notice—a principle deeply rooted in the application of the discovery rule both to fraud claims more generally and

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[18] As explained in petitioners' opening brief (at 49-50), this case epitomizes that phenomenon. Although respondents have never specified the exact amount they are seeking in damages, they do not dispute that it runs into the *billions* of dollars largely because their delay in filing suit allowed them to expand the size of their class. See, *e.g.*, Resp. C.A. Reply Br. 24 (noting that Merck's market capitalization declined by approximately $10 billion in October 2003 and by another $37.2 billion between September 30 and November 1, 2004).

to securities-fraud claims specifically. See p. 3, *supra*. The government contends (Br. 24) that the principle of inquiry notice would still play a role, because a court would have to determine the point at which the plaintiff was on inquiry notice before determining when a hypothetical plaintiff would have discovered facts sufficient to file a complaint. It is hard to see why that is so. A court could simply skip to the latter inquiry, because it in no way depends on what the actual plaintiff knew and when he knew it. A "hypothetical plaintiff" approach would therefore effectively strip the concept of inquiry notice out of the discovery rule in Section 1658(b)—and, indeed, would further threaten to require *actual* discovery to trigger the limitations period. See p. 15, *supra*.

c. Finally, and perhaps most importantly, a "hypothetical plaintiff" approach would lead to potentially grave difficulties in application, because it would mandate open-ended speculation about what a reasonably diligent investigation would have entailed. Even the government acknowledges that such an approach would "often involve some approximation." Br. 23. In fact, it would generate collateral litigation and disserve the need, on the part of plaintiffs and defendants alike, for clarity and consistency in the determination of the applicable limitations period.

Respondents recognize (Br. 29) that, under the "hypothetical plaintiff" approach, the availability of a limitations defense will usually need to be determined by a jury, rather than by the court on a motion to dismiss or motion for summary judgment—with the burden on the defendant to prove that an investigation would have been successful. As a preliminary matter, it is hard to imagine that a defendant that is contesting a claim of securities fraud would want to argue to the same jury that a hypothetical plaintiff would surely have discovered the al-

leged fraud. But that is an academic point, because, as respondents are doubtless aware, securities-fraud cases hardly ever go to trial: even where the underlying claims are meritless, they almost invariably settle if the plaintiffs are able to survive dispositive motions. And if courts could no longer readily resolve the limitations defense on those motions (as they now routinely do, see, *e.g.*, *Dodds*, 12 F.3d at 352 n.3), the practical consequence would be to take that defense off the table altogether. That, we respectfully submit, is respondents' real objective here, and that is what respondents will achieve if their proposed rule is adopted.[20]

* * * * *

In the end, respondents are left accusing Merck of "concocting" the naproxen hypothesis or possessing some unidentified "internal data" demonstrating Vioxx's risks. Those accusations are unfounded. But they should not obscure the fact that the Court is deciding how the limitations period should operate for *all* private securities-fraud claims, regardless of their merit—a type of claim, it bears remembering, for which Congress has never expressly provided. A ruling in petitioners' favor, whether on the question presented or the broader question on which respondents focus, would preserve an appropriate balance between defendants' interest in repose

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[20] Because the court of appeals held that respondents were not on inquiry notice, it did not reach the issue of when a hypothetical plaintiff would have completed an investigation (or whether respondents possessed the means of doing so). That issue, moreover, has not been litigated at any stage of this case. Should the Court choose to reach the issue and adopt either the government's or respondents' approach, therefore, it should remand for the lower courts to consider that issue in the first instance.

and plaintiffs' interest in remediation. And it would in no way restrict the ability of reasonably diligent investors to bring suit. The court of appeals' specific holding on inquiry notice cannot be defended. This Court should correct the court of appeals' error and reverse the judgment below.

* * * * *

For the foregoing reasons and those stated in petitioners' opening brief, the judgment of the court of appeals should be reversed.

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NOVEMBER 2009

SUPPLEMENTAL BRIEF

No. 08-905

Supreme Court, U.S.
FILED
MAY 11 2009
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

MERCK & CO., INC., *ET AL.*,

Petitioners,

v.

RICHARD REYNOLDS, STEVEN LEVAN, JEROME HABER, *ET AL.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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May 11, 2009

Pursuant to Supreme Court Rule 15.8, Petitioners respectfully submit this supplemental brief in response to two briefs filed recently in *Trainer Wortham & Co. v. Betz*, No. 07-1489, which poses the same Question Presented as the petition here. *See* Brief for the United States as Amicus Curiae (Apr. 22, 2009) ("U.S. Br."); Supplemental Brief in Support of Petition (Apr. 30, 2009) ("*Betz* Supp. Br.").

The Government recognizes that the Third Circuit's opinion below, like the Ninth Circuit's opinion in *Betz*, "squarely held" that inquiry notice arises only when a plaintiff possesses evidence that the defendant acted with scienter.[1] (*See* U.S. Br. at 17.) As the Government observes, this holding places the Third Circuit at odds with the majority of the Courts of Appeals, which are sharply divided in multiple ways on the proper interpretation of the inquiry notice standard. (*See id.* at 14-17.) The Government also recognizes that this petition is a superior vehicle to *Betz* for addressing these critical divisions. (*See id.* at 18 & n.6.)

Now that the United States has opined both on the issues presented by this petition and on the petition's suitability as a vehicle for exploring those is-

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[1] The *Betz* petitioners' argument to the contrary (*see Betz* Supp. Br. at 6) ignores the clear language in the opinion below and in the Third Circuit's subsequent opinion in *Alaska Electrical Pension Fund v. Pharmacia Corp.*, 554 F.3d 342 (3d Cir. 2009). (*See* Reply Brief for Petitioners at 3-4, 6-7 (Apr. 7, 2009).)

sues, Petitioners respectfully request that the Court grant the petition.[2]

CONCLUSION

The petition for a writ of *certiorari* should be granted.

May 11, 2009

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[2] Petitioners agree with the *Betz* petitioners that the Court should hold the *Betz* petition if *certiorari* is granted in the present case. (*See Betz* Supp. Br. at 11-12.)

SUPPLEMENTAL BRIEF

FILED
MAY 13 2009
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 08-905

IN THE
Supreme Court of the United States

MERCK & CO., INC., ET AL.,
Petitioners,

v.

RICHARD REYNOLDS, ET AL.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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May 13, 2009

Pursuant to this Court's Rule 15.8, Respondents respectfully submit this supplemental brief in response to the Supplemental Brief for Petitioners filed May 11, 2009, concerning the Brief for the United States as Amicus Curiae filed in *Trainer Wortham & Co. v. Betz*, No. 07-1489, on April 22, 2009 ("U.S. Br."). The Solicitor General opined that there was a split between the circuits concerning (i) whether an investor is on "inquiry notice" regarding a claim of securities fraud when he has reason to suspect that the defendant has made a false statement, but has no reason to suspect that the defendant made the false statement with scienter; and (ii) when the statute of limitations begins to run once an investor is on "inquiry notice" of potential securities fraud. The Solicitor General further opined that *Betz* would not be an appropriate vehicle for resolving these issues because the plaintiff in that case had notice of both falsity and scienter more than two years prior to filing suit. *See* U.S. Br. 18. In a footnote, the Solicitor General suggested that *Merck* might represent a better vehicle for resolving these issues. *See id.* at 18 n.6. The Solicitor General's footnote suggestion appears to have been based on a misunderstanding of the basis of the *Merck* decision.

The Third Circuit in *Merck* considered only indicia of *falsity*, not *scienter*. Indeed, the Third Circuit's only references to scienter are to recite the pleading requirements for securities actions, *see* Pet. App. 30a n.12, and to state that it would "not express any opinion" as to whether scienter had been pleaded in *Merck*, *see id.* at 20a n.8. The background for the Third Circuit's decision, as Respondents explained in their Brief in Opposition ("Resp. Br."), is that the complaint in *Merck* alleges that Petitioners falsely

represented their *belief* as to the likely explanation for the results of the VIGOR trial. *See* Resp. Br. 5; Pet. App. 33a-34a ("[a]ppellants' theory in the complaint is that Merck's statements about the validity of the naproxen hypothesis were falsely-held statements of opinion or belief"). Statements of *belief* are generally deemed "false" for the purposes of a securities fraud claim if the speaker "did not hold the beliefs or opinions expressed." *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1090 (1991); *see also* Pet. App. 33a. Thus, to determine whether Merck investors had inquiry notice of *falsity*, the Third Circuit examined whether investors had inquiry notice that Merck "did not hold the beliefs or opinions" that it claimed to have concerning the naproxen hypothesis.

The Third Circuit made the determination that the earliest time investors could have been placed on inquiry notice that Merck did not believe the naproxen hypothesis was in Fall 2003, when the results of the Brigham/Harvard study were made public. At that point, investors were on inquiry notice that Merck's statements of belief could be *false*. *See* Pet. App. 47a ("On the record before us, there is no reason to suspect that Merck *did not believe* the naproxen hypothesis until the Harvard study in 2003 revealed an increased risk of heart attack in patients taking Vioxx compared with patients taking Celebrex and placebo.") (emphasis added). Thus, this is not a case where the distinction between inquiry notice based solely on *falsity*, and inquiry notice based on *falsity plus scienter*, would make a difference, because, under either standard, the Third Circuit found that notice of *falsity* was not present until 2003. Under either

interpretation of the inquiry notice standard, therefore, the result in *Merck* would be the same.

Petitioners also incorrectly assert that the Solicitor General "recognizes that the Third Circuit's opinion below [in *Merck*] . . . 'squarely held' that inquiry notice arises only when a plaintiff possesses evidence that the defendant acted with scienter." Suppl. Brief 1. This assertion is simply not true. The Solicitor General quoted a *subsequent* Third Circuit opinion, *Alaska Elec. Pension Fund v. Pharmacia Corp.*, 554 F.3d 342, 348 (3d Cir. 2009), for the proposition that "inquiry notice, in securities fraud suits, requires storm warnings indicating that defendants acted with scienter." U.S. Br. 17. (A petition for certiorari in that case is pending before this Court, No. 08-1315 (U.S. filed Apr. 22, 2009).) The Third Circuit's opinion in *Merck* makes no such statement – indeed, no such statement was necessary for the Court's judgment – because the court was only considering the *falsity* of a statement of belief. *See* Pet. App. 33a.

Moreover, the Solicitor General's footnoted discussion of *Merck* does not take into account *Merck*'s unusual factual scenario: a securities fraud claim based on a misrepresentation of an *opinion* in the context of a *scientific debate*. This unusual constellation of circumstances – which arises in part because of the complexity of the underlying scientific question involved, and the lack of definitive public studies of VIOXX and naproxen's effects on cardiovascular events – makes it difficult for this Court to reach a conclusion as to the standard for inquiry notice in a manner that will have general applicability across multiple, and dissimilar, fact patterns. For this reason, the Court should await a less factually unusual

case to opine on the standards for inquiry notice in securities fraud cases.

Because the Third Circuit found that Respondents had no storm warnings that Merck's statements of opinions were false, it did not need to (and did not) address the issue of when the statute of limitations begins to run once a potential plaintiff is on "inquiry notice." *See* Resp. Br. 2. Because there is no ground to disturb that ruling, this case would not present a vehicle for addressing the issue of when the statute of limitations begins to run once an investor is on "inquiry notice" of potential securities fraud.

Respondents thus respectfully request that the Court deny the petition.

Respectfully submitted,

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May 13, 2009

AMICUS CURIAE BRIEF

No. 08-905

In the Supreme Court of the United States

MERCK & CO., INC., ET AL., PETITIONERS

v.

RICHARD REYNOLDS, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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QUESTIONS PRESENTED

The federal statute of limitations for private securities-fraud actions provides that a plaintiff must file suit within "[two] years after the discovery of the facts constituting the violation," but not later than "[five] years after such violation." 28 U.S.C. 1658(b)(1) and (2). The lower courts have uniformly construed the term "discovery" in that provision to encompass constructive as well as actual discovery, so that suit must be filed within two years after the plaintiff, in the exercise of reasonable diligence, ought to have discovered the "facts constituting the violation." The point at which the plaintiff was sufficiently alerted to the possibility of wrongdoing that a reasonably diligent investor in his position would have undertaken further investigation is commonly referred to as "inquiry notice." The questions presented are as follows:

1. Whether, when the two-year limitations period is triggered by constructive discovery, the period begins to run when the plaintiff is first placed on "inquiry notice," or only after an investor who has previously been placed on inquiry notice should have discovered the violation by way of a diligent investigation.

2. Whether a potential plaintiff is on "inquiry notice" of possible fraud in violation of the securities laws whenever he suspects that the defendant has made a false statement, or only when he has reason to suspect that the defendant made the misstatement with the scienter necessary to constitute a violation of the securities laws.

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In the Supreme Court of the United States

No. 08-905

MERCK & CO., INC., ET AL., PETITIONERS

v.

RICHARD REYNOLDS, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BRIEF OF THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENTS

INTEREST OF THE UNITED STATES

This case concerns the proper application of 28 U.S.C. 1658(b), the federal statute of limitations for private securities-fraud claims. Meritorious private securities-fraud actions are an essential supplement to criminal prosecutions and civil enforcement actions brought by the United States and the Securities and Exchange Commission (SEC). The government therefore has a strong interest in Section 1658(b)'s proper construction. At the Court's invitation, the United States previously filed a brief amicus curiae in *Trainer Wortham & Co.* v. *Betz*, petition for cert. pending, No. 07-1489 (filed May 27, 2008), which raised substantially similar issues.

STATEMENT

1. Section 10(b) of the Securities Exchange Act of 1934 (1934 Act) makes it unlawful to "use or employ, in connection with the purchase or sale of any security * * *, any manipulative or deceptive device or contrivance in contravention of" rules and regulations prescribed by the SEC. 15 U.S.C. 78j(b). The SEC's Rule 10b-5 implements Section 10(b) by declaring it unlawful, "in connection with the purchase or sale of any security," to (a) "employ any device, scheme, or artifice to defraud"; (b) "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made * * * not misleading"; or (c) "engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person." 17 C.F.R. 240.10b-5.

This Court has construed Section 10(b) to afford an implied right of action. See, *e.g.*, *Dura Pharm., Inc.* v. *Broudo*, 544 U.S. 336, 341 (2005). In order to establish a Section 10(b) or Rule 10b-5 violation, a private plaintiff must prove the defendant made a material misrepresentation or omission with scienter—"a mental state embracing intent to deceive, manipulate, or defraud." *Ernst & Ernst* v. *Hochfelder*, 425 U.S. 185, 194 n.12 (1976). To recover under the implied cause of action, a plaintiff must show, beyond a securities violation, that he relied on the defendant's misrepresentation and suffered economic loss as a result. *Dura*, 544 U.S. at 341-342. In the absence of an express statute of limitations, this Court held in *Lampf, Pleva, Lipkind, Prupis & Petigrow* v. *Gilbertson*, 501 U.S. 350 (1991) (*Lampf*), that Section 10(b) claims must be brought within the earlier of one year "after the discovery of the facts constituting the violation" or three years after the violation, *id.* at

364. The Court borrowed that language from limitations periods Congress had provided for express causes of action under the Securities Act of 1933 (1933 Act), 15 U.S.C. 77a *et seq.*, and the 1934 Act. *Lampf*, 501 U.S. at 359-360 & nn.6-7, 364 n.9 (citing 15 U.S.C. 77m, 78i(e), 78r(c)).

Congress adopted the Private Securities Litigation Reform Act of 1995 (PSLRA), Pub. L. No. 104-67, 109 Stat. 737, in response to the problem of abusive private securities litigation, including plaintiff lawyers' "race to the courthouse" after only "minimal time preparing complaints," often based on no more than a stock-price drop or "a failed product development project," S. Rep. No. 98, 104th Cong., 1st Sess. 8, 10-11 (1995). See H.R. Conf. Rep. No. 369, 104th Cong., 1st Sess. 31 (1995) (criticizing "the routine filing of lawsuits * * * without regard to any underlying culpability of the issuer"). *Inter alia*, the PSLRA requires a private securities-fraud complaint to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. 78u-4(b)(2).

In 2002, Congress established an express federal statute of limitations to govern securities-fraud claims. Sarbanes-Oxley Act, Pub. L. No. 107-204, § 804, 116 Stat. 801 (28 U.S.C. 1658(b)). Section 1658(b) applies to any "private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws." Like the limitations periods borrowed by the Court in *Lampf*, the Sarbanes-Oxley Act established both a period of repose, 28 U.S.C. 1658(b)(2), and a limitations period running "after the discovery of the facts constituting the violation," 28 U.S.C. 1658(b)(1). Congress lengthened the time available to bring suit, how-

ever, by extending the limitations period to two years and the period of repose to five.

The Senate Judiciary Committee explained that *Lampf's* one-year period encouraged "victims to race into court." S. Rep. No. 146, 107th Cong., 2d Sess. 9 (2002). The Committee contemplated that, in contrast to the one-year period, the two-year period would allow a plaintiff "to file a complaint under a heightened pleading standard, survive[] a motion to dismiss, begin[] discovery, and learn[] that an additional wrongdoer or theory should be added to the case." *Ibid.*

2. Merck developed Vioxx as one of a new class of painkillers with less harmful gastrointestinal (GI) side-effects. Pet. App. 5a. The market viewed Vioxx as having blockbuster potential. *Ibid.* To demonstrate Vioxx's superior GI safety, Merck undertook a large-scale study—the Vioxx Gastrointestinal Outcomes Research (VIGOR) study—comparing Vioxx to naproxen, the ingredient in other pain relievers. *Id.* at 6a. The results of the study did show greater GI safety, but also showed that Vioxx users suffered significantly more heart attacks than naproxen users. *Ibid.* To explain that discrepancy, Merck's public statements advanced the "naproxen hypothesis"—*i.e.*, that the lower incidence of cardiac events for patients taking naproxen was attributable to a beneficial effect of naproxen rather than to any harmful effect of Vioxx. *Id.* at 7a. In a press release about the study, Merck noted, however, that such an effect "had not been observed previously in any clinical studies for naproxen." J.A. 291.

In September 2001, the Food and Drug Administration (FDA) issued a Warning Letter informing Merck that its marketing of Vioxx was "false, lacking in fair balance, or otherwise misleading in violation of the Fed-

eral Food, Drug, and Cosmetic Act." J.A. 339. The FDA acknowledged that the naproxen hypothesis was "a possible explanation" for the VIGOR study's data concerning cardiac events, but faulted Merck for failing to balance presentation of that hypothesis with the alternative "reasonable explanation, that Vioxx may have prothrombotic properties." J.A. 340. The FDA directed Merck to issue a corrective letter to healthcare providers. J.A. 353.

The Brigham and Women's Hospital in Boston conducted a study funded by Merck (the Harvard Study) to test Vioxx's cardiac effect against Celebrex, another painkiller, and a placebo. On October 30, 2003, a Wall Street Journal (WSJ) article cited the Harvard Study as having "found an increased risk of heart attack in patients taking Vioxx compared with patients taking Celebrex and placebo." Pet. App. 18a. According to the article, the increased relative risk of heart attack, between 30 and 90 days, was 37%. *Ibid.*

3. On November 6, 2003, a week after the WSJ article, the first securities class-action complaint regarding Vioxx's safety was filed. C.A. App. 1218 (Pringle Compl.). The complaint characterized the October 30 WSJ article, and another from October 22 reporting that Vioxx sales were "suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks," as having disclosed the truth about Vioxx's increased cardiac risk. *Id.* at 1245-1248. Apart from recounting these news articles, the complaint made only generalized allegations of scienter. *Id.* at 1248.

On September 30, 2004, Merck withdrew Vioxx from the market, based on a new study indicating "an increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy." Pet. App.

19a (internal quotation marks omitted). On November 1, 2004, the WSJ reported that "internal Merck e-mails and marketing materials as well as interviews with outside scientists show that the company fought forcefully for years to keep safety concerns from destroying the drug's commercial prospects." *Ibid.*

Ten new securities class-action complaints were filed during the next three months. See C.A. App. 121-174 (docket sheets). The Judicial Panel on Multi-District Litigation directed that all the lawsuits be centralized in the District of New Jersey. J.A. 17.

On June 15, 2005, after the cases were consolidated, respondents filed a 453-paragraph Corrected Consolidated And Fourth Amended Class Action Complaint. J.A. 20-264. The Fourth Amended Complaint cites the November 1, 2004, WSJ article as having "revealed the truth concerning [petitioners'] wrongful conduct and their actual knowledge of the truth regarding Vioxx." J.A. 197.

4. Petitioners moved to dismiss the Fourth Amended Complaint, arguing that the suit was time-barred because information suggesting Merck's possible fraud had been released to the public more than two years before the November 6, 2003, filing of the first complaint. The district court granted the motion. Pet. App. 62a-99a. The court held that respondents were on "inquiry notice" of Merck's possible fraud by October 9, 2001. *Id.* at 85a. The court characterized the September 2001 FDA Warning Letter as having, "in no uncertain terms, * * * accuse[d] Merck of misrepresentation by endorsing the naproxen hypothesis as fact." *Ibid.* The court also noted "numerous articles" (the last of which appeared on October 9, 2001) reporting "the competing prothrombotic hypothesis * * * that

VIOXX in fact increased the risk of heart attack." *Id.* at 87a; see *id.* at 85a, 89a.

Because respondents were on inquiry notice 25 months before the first Vioxx lawsuit was filed, and had not made diligent investigation thereafter, the district court held their suit untimely. Pet. App. 97a-98a. The court concluded that "a reasonable investor would have discovered the basis for his fraud claims against Merck * * * within the two years following the storm warnings which existed before November 6, 2001." *Id.* at 98a.

5. The court of appeals reversed. Pet. App. 1a-61a. The court held that the timeliness of the complaint depended on when respondents knew or should have known of the basis of their claims, which, in turn, depended on when they had "inquiry notice." *Id.* at 22a. The court defined "inquiry notice" as "sufficient information of possible wrongdoing * * * to excite storm warnings of culpable activity." *Id.* at 28a (quoting *Benak* v. *Alliance Capital Mgmt., L.P.*, 435 F.3d 396, 400 (3d Cir. 2006)).

The court of appeals held that respondents were not on "inquiry notice" of Merck's possible fraud before November 6, 2001, and that their initial complaint was therefore timely. The court stressed that the FDA Warning Letter "did not charge that the naproxen hypothesis was wrong or that Merck did not believe in [its] validity," but only directed Merck to be more clear about the competing hypothesis, which was already publicly known. Pet. App. 43a. The court also rejected the district court's conclusion that "storm warnings" had arisen from the October 9 New York Times article. *Id.* at 45a-46a. The court explained that, although a Merck official quoted in that article had acknowledged the competing explanations for the VIGOR study results, he had reaf-

firmed Merck's view that the naproxen hypothesis is "the likeliest interpretation." *Id.* at 45a. The court of appeals concluded that "there [was] no reason to suspect that Merck did not believe the naproxen hypothesis until the Harvard Study in 2003 revealed an increased risk of heart attack" for Vioxx compared to Celebrex and a placebo. *Id.* at 47a.

Judge Roth dissented. Pet. App. 49a-61a. She would have held that the FDA Warning Letter put respondents on inquiry notice of a possibly fraudulent misrepresentation. *Id.* at 55a. Because respondents had conducted no investigation after the FDA Warning Letter, Judge Roth would have held that the limitations period expired two years thereafter, before the first class-action complaint was filed. *Id.* at 61a.

SUMMARY OF ARGUMENT

A. Section 1658(b)(1)'s two-year limitations period does not begin to run until the plaintiff has actually discovered, or in the exercise of reasonable diligence ought to have discovered, facts demonstrating that all the elements of a securities-fraud violation can be established. In particular, because scienter is an essential element of a Section 10(b) violation, the term "facts constituting the violation" is best construed to include facts demonstrating that the defendant possessed the requisite mental state. And while the term "discovery" in Section 1658(b)(1) encompasses constructive as well as actual discovery, constructive discovery is properly deemed to occur at the time a reasonably diligent investor would have unearthed the relevant facts—not when such an investor would *begin* investigating. That reading is confirmed by 15 U.S.C. 77m, which establishes an express constructive-discovery rule that provides the best evi-

dence of Congress's intent as to the proper application of constructive-discovery principles in the securities context.

Petitioners are therefore wrong in arguing that Section 1658(b)(1)'s limitations period runs from the time an investor is placed on "inquiry notice." Petitioners' alternative argument—that the limitations period should run from the time of "inquiry notice" at least when the plaintiff fails to exercise reasonable diligence in investigating suspicious circumstances—is likewise incorrect. In such cases too, the limitations period should run from the time a diligent investor would have discovered the facts constituting the violation. When Congress specifies the time at which a limitations period will commence, courts have no authority to direct that the period run from an earlier date, even to "punish" dilatory plaintiffs. If Congress had wanted to modify the limitations period in this way, Congress could have done so. Here, it did not.

B. A plaintiff is placed on "inquiry notice" of a possible Section 10(b) violation only if the available information suggests that a defendant's possible misrepresentation was made with scienter. The purpose of the "inquiry notice" concept is to identify the point in time when a reasonably diligent investor would have commenced an investigation. Because scienter is an essential element of a Section 10(b) violation, an investor who suspects that a misrepresentation was made, but has no reason to believe that it was anything other than an innocent mistake, cannot fairly be charged with lack of reasonable diligence if he declines to inquire further.

C. The court of appeals correctly held that respondents' suit was timely filed. Although numerous documents (including the FDA Warning Letter on which petitioners principally rely) made clear that the naproxen

hypothesis was unproven and open to debate, those documents did not place respondents on "inquiry notice" because they gave respondents no reason to suspect that Merck's statement of its belief in the naproxen hypothesis was made with scienter. In any event, even if the FDA letter would have led a reasonably diligent investor to suspect that Merck had made knowing misrepresentations with regard to the naproxen hypothesis, petitioners identify no means by which respondents could have confirmed those suspicions before November 6, 2001.

ARGUMENT

THIS ACTION IS TIMELY BECAUSE RESPONDENTS NEITHER KNEW, NOR REASONABLY COULD HAVE KNOWN, THE FACTS CONSTITUTING PETITIONERS' ALLEGED SECTION 10(b) VIOLATION MORE THAN TWO YEARS BEFORE FILING SUIT

Under 28 U.S.C. 1658(b), a federal securities-fraud action must be commenced "not later than the earlier of" the following two dates: "2 years after the discovery of the facts constituting the violation," 28 U.S.C. 1658(b)(1), or "5 years after such violation," 28 U.S.C. 1658(b)(2). Petitioners contend that the two-year period specified in Section 1658(b)(1) runs from the date when "a plaintiff possesses a quantum of information sufficiently suggestive of wrongdoing that he should conduct a further inquiry to confirm the existence of his claim." Pet. Br. 20 (defining inquiry notice); *id.* at 40 ("inquiry notice [sh]ould always trigger the running of the limitations period"). Petitioners' theory cannot be reconciled with the text of Section 1658(b)(1). Acceptance of that approach would also subvert the balance struck by Congress between (a) encouraging potential securities-fraud plaintiffs to conduct prompt and diligent investigations,

(b) ensuring that such plaintiffs have adequate time to conduct appropriate inquiries and to pursue litigation if their investigations reveal a sound basis to infer wrongdoing, and (c) discouraging "strike suits" premised on mere suspicion of fraud.

A. Section 1658(b)(1)'s Two-Year Period Begins To Run Only After The Plaintiff Discovers Or Should Have Discovered Facts Demonstrating That All Elements Of A Securities-Fraud Violation Can Be Established

Congress adopted Section 1658(b) in response to this Court's decision in *Lampf*. In *Lampf*, the Court held that securities-fraud claims under Section 10(b) and SEC Rule 10b-5 were governed by a uniform federal limitations period and must be brought within the earlier of one year "after the discovery of the facts constituting the violation" or three years after the violation, the latter of which constituted an absolute period of repose. 501 U.S. at 364. The Court borrowed that language from the limitations periods that Congress had provided in 15 U.S.C. 77m, 78i(e), and 78r(c), for express causes of action under the 1933 and 1934 Acts. See *Lampf*, 501 U.S. at 359-360 & nn.6-7, 364 n.9.

In 2002, Congress extended the limitations period from one to two years and extended the period of repose from three to five years, while retaining *Lampf*'s trigger for the limitations period to begin running—"discovery of the facts constituting the violation." 28 U.S.C. 1658(b)(1). Proper application of Section 1658(b)(1) requires the Court (1) to construe the phrase "facts constituting the violation" and (2) to identify the point at which "discovery" of those facts occurs.

1. The term "facts constituting the violation" in Section 1658(b)(1) means facts demonstrating that the defendant has violated the securities laws

To establish a violation of Section 10(b), a plaintiff must prove that the defendant made a material misrepresentation or omission in connection with the purchase or sale of a security, and that "the defendant acted with scienter, 'a mental state embracing intent to deceive, manipulate, or defraud.'" *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007) (internal quotation marks and citation omitted); see *Aaron* v. *SEC*, 446 U.S. 680, 691 (1980) (explaining that "scienter is an element of a violation of § 10(b) and Rule 10b-5").[1] Although scienter must often be established circumstantially, it is nonetheless a "fact" that must be pleaded and proved. Cf. *Edgington* v. *Fitzmaurice*, 29 Ch. D. 459, 483 (Eng. 1885) ("[T]he state of a man's mind is as much a fact as the state of his digestion."). The phrase "facts constituting the violation" in Section 1658(b)(1) should be construed in light of those substantive legal requirements. Thus, the two-year limitations period established by Section 1658(b)(1) begins to run upon the plaintiff's discovery of facts demonstrating that the defendant has made the sort of material misrepresentation or omission that Section 10(b) covers, with the requisite mental state.

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[1] To recover under the private right of action implied under Section 10(b) and Rule 10b-5, a private plaintiff must establish elements beyond those required for a "violation" of Section 10(b), such as reliance, loss, and loss causation. See *Dura*, 544 U.S. at 341-342. We agree with petitioners (Br. 25, 29) that facts bearing on those additional requirements are not naturally viewed as among the "facts constituting the violation" within the meaning of Section 1658(b)(1).

Construing the statute in that fashion is consistent with the PSLRA. That statute requires securities-fraud plaintiffs who sue as class representatives to "specify each statement [of the defendant] alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. 78u-4(b)(1). In addition, in any private suit "in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall * * * state with particularity facts giving rise to a strong inference that the defendant acted with the requisite state of mind." 15 U.S.C. 78u-4(b)(2). A primary purpose of the PSLRA's heightened pleading requirement with respect to scienter is to discourage plaintiffs from charging as securities fraud every statement that has turned out to be false. H.R. Conf. Rep. No. 369, at 31. Consistent with that enactment, Section 1658(b)(1)'s limitations period should begin to run when the plaintiff discovered or ought to have discovered facts that, if set out in a complaint, would allege scienter, as well as all other elements of a statutory violation, with sufficient specificity to survive a motion to dismiss.[2]

Petitioners contend (Br. 41) that "the phrase 'facts constituting the violation' [in Section 1658(b)(1)] is properly understood to reach only the core nucleus of facts

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[2] *Rotella* v. *Wood*, 528 U.S. 549 (2000), did not, as petitioners contend (Br. 31), reject considering pleading standards when construing statutes of limitations. In deciding when the limitations period should start to run under RICO, the Court reasoned that because many civil RICO claims do not involve fraud, there was an "insufficient connection between civil RICO and fraud" to warrant considering Fed. R. Civ. P. 9(b)'s heightened pleading standards. *Rotella*, 528 U.S. at 557. By contrast, *every* Rule 10b-5 complaint must surmount heightened pleading standards.

concerning the defendant's *conduct*, separate and apart from the fact of the defendant's *state of mind*." But where, as under Section 10(b), an innocent misstatement does not violate the applicable law, facts suggesting that such a misstatement has occurred are not naturally characterized as "facts constituting [a] violation." That inference is reinforced by Section 1658(b)(1)'s application only to private suits "that involve[] a claim of fraud, deceit, manipulation, or contrivance." 28 U.S.C. 1658(b). Because the class of suits covered by Section 1658(b)(1) is defined in part by reference to the defendant's dishonest intent, it is particularly clear that the "facts constituting the violation" include facts demonstrating the requisite scienter.

And indeed, petitioners themselves do not construe the phrase "facts constituting the violation" as limited to facts concerning what the defendant actually did. Petitioners decline to contend that Section 1658(b)(1)'s two-year limitations period commenced to run as soon as respondents discovered that Merck had endorsed the naproxen hypothesis. Rather, petitioners argue that the triggering "discovery" occurred upon the publication of materials (the FDA Warning Letter and various newspaper articles) suggesting that the naproxen hypothesis was false. But if the phrase "facts constituting the violation" encompasses facts that demonstrate the falsity of previously known statements, so too must that phrase encompass facts that demonstrate the mental state with which such statements were made. Both sets of facts go to the illegality, rather than mere existence, of the defendant's statements, and neither is any more indispensable than the other in establishing that illegality. Because falsity and scienter are both elements of a Section 10(b)

violation, there is no basis for distinguishing between the facts demonstrating the two.

2. Section 1658(b)(1)'s two-year limitations period can be triggered by either actual or constructive discovery of the "facts constituting the violation," but is not triggered by mere suspicion of illegality

a. Section 1658(b)(1)'s reference to "the discovery of the facts constituting the violation" most obviously covers the *actual* discovery by the plaintiff of the facts constituting the defendant's violation of the securities laws. In addition, however, the term "discovery" in this provision is properly read to encompass constructive discovery. When Congress enacted Section 1658(b)(1), it was well-established that the limitations period adopted in *Lampf* could commence to run either upon actual discovery of the relevant facts or at the time of constructive discovery—*i.e.*, the time when the plaintiff should have discovered the violation in the exercise of reasonable diligence.

In *Lampf*, the Court referenced Section 13 of the Securities Act of 1933, 15 U.S.C. 77m, which includes an express constructive-discovery rule, as one source of the limitations period the Court adopted. See *Lampf*, 501 U.S. at 360 n.7. Under Section 13, the limitations period begins to run "after the discovery of the untrue statement or the omission, *or after such discovery should have been made by the exercise of reasonable diligence.*" 15 U.S.C. 77m (emphasis added). Between this Court's decision in *Lampf* and the enactment of Section 1658(b)(1), the courts of appeals uniformly applied a rule of constructive discovery, often by express reference to

Section 13.[3] This Court likewise construed similarly worded limitations provisions to encompass constructive discovery. *E.g.*, *Kirby* v. *Lake Shore & Mich. S. R.R.*, 120 U.S. 130, 134-135, 138 (1887) (construing statute providing that action for fraud is "not to be deemed to have accrued until the discovery by the aggrieved party of the facts constituting the fraud" to mean that the statute did not run "until after such fraud was or should, with due diligence, have been discovered") (quoting N.Y. Code of Procedure § 91(6), at 70 (Voorhies' 5th ed. 1857)). Congress can therefore be presumed to have intended that the same construction be given to Section 1658(b)(1). See, *e.g.*, *Commissioner* v. *Keystone Consol. Indus., Inc.*, 508 U.S. 152, 159 (1993).

b. When the two-year limitations period is triggered by constructive rather than actual discovery of the securities violation, the court should typically undertake a two-step analysis to calculate when the limitations period began to run. First, the court identifies the point at which the plaintiff received information sufficiently suggestive of possible wrongdoing that a reasonable investor would have undertaken further investigation to de-

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[3] See *Cooperativa de Ahorro y Credito Aguada* v. *Kidder, Peabody & Co.*, 129 F.3d 222, 224 (1st Cir. 1997); *Dodds* v. *CIGNA Sec., Inc.*, 12 F.3d 346, 349 (2d Cir. 1993) (citing Section 13), cert. denied, 511 U.S. 1019 (1994); *Mathews* v. *Kidder, Peabody & Co.*, 260 F.3d 239, 251 (3d Cir. 2001); *Brumbaugh* v. *Princeton Partners*, 985 F.2d 157, 162 (4th Cir. 1993); *Topalian* v. *Ehrman*, 954 F.2d 1125, 1134-1135 (5th Cir.), cert. denied, 506 U.S. 825 (1992); *New Eng. Health Care Employees Pension Fund* v. *Ernst & Young, LLP*, 336 F.3d 495, 500 (6th Cir. 2003) (citing Section 13), cert. denied, 540 U.S. 1183 (2004); *Law* v. *Medco Research, Inc.*, 113 F.3d 781, 785-786 (7th Cir. 1997) (same); *Ritchey* v. *Horner*, 244 F.3d 635, 638-639 (8th Cir. 2001) (same); *Sterlin* v. *Biomune Sys.*, 154 F.3d 1191, 1199-1202 (10th Cir. 1998) (same); *Theoharous* v. *Fong*, 256 F.3d 1219, 1228 (11th Cir. 2001).

termine whether the defendant had violated the securities laws. That point is commonly referred to as "inquiry notice."[4]

Second, the court must ascertain at what time "the investor, in the exercise of reasonable diligence, should have discovered the facts constituting the alleged fraud." *Betz* v. *Trainer Wortham & Co*, 519 F.3d 863, 876 (9th Cir. 2008), petition for cert. pending, No. 07-1489 (filed May 27, 2008). It is "[t]he answer to that second question" which identifies the date on which "the statute of limitations began to run." *Ibid.*; accord, *e.g.*, *New Eng. Health Care Employees Pension Fund* v. *Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003), cert. denied, 540 U.S. 1183 (2004); *Sudo Props., Inc.* v. *Terrebonne Parish Consol. Gov't*, 503 F.3d 371, 377-378 (5th Cir. 2007); *Young* v. *Lepone*, 305 F.3d 1, 9-10 (1st Cir. 2002); *Rothman* v. *Gregor*, 220 F.3d 81, 97 (2d Cir. 2000); *Sterlin* v. *Biomune Sys.*, 154 F.3d 1191, 1201 (10th Cir. 1998); *Howard* v. *Haddad*, 962 F.2d 328, 330 (4th Cir. 1992) (Powell, J.).

Petitioners argue (Br. 40) that "the date on which the plaintiff was on inquiry notice [should] always trigger the running of the limitations period." That approach cannot be squared with the language of Section 1658(b)(1). Section 1658(b)(1)'s two-year limitations

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[4] The terminology used by the courts has not been uniform, and some use "inquiry notice" to refer to what is described here and by petitioners as "constructive discovery." See, *e.g.*, *Berry* v. *Valence Tech., Inc.*, 175 F.3d 699, 704 (9th Cir.) (describing as "inquiry notice" the rule that, after investigation is triggered, the "limitations period begins to run once the investor, in the exercise of reasonable diligence, should have discovered the facts underlying the alleged fraud") (quoting *Sterlin*, 154 F.3d at 1201), cert. denied, 528 U.S. 1019 (1999); S. Rep. No. 146, at 29 (views of dissenting Senators).

period begins to run not when a reasonable investor would become suspicious or commence further investigation, but only "after the discovery of the facts constituting the violation." Even in a case involving constructive discovery, in which the court must determine when a reasonably diligent investor *would have* discovered the relevant facts, the point at which a diligent investigation would have borne fruit will inevitably be later than the point at which the investigation should have commenced. There is consequently no textual basis for petitioners' view that the two-year limitations period begins to run when the plaintiff is placed on "inquiry notice." No more than actual discovery occurs when an investigation commences does constructive discovery occur when an investigation should have done so.

The error in petitioners' approach is confirmed by 15 U.S.C. 77m, one of the limitations periods on which the Court in *Lampf* relied (see 501 U.S. at 360 & n.7), which establishes an express constructive-discovery rule. Section 77m states that "[n]o action shall be maintained to enforce any liability created under section 77k or 77*l*(a)(2) of this title unless brought within one year after the discovery of the untrue statement or the omission, *or after such discovery should have been made by the exercise of reasonable diligence*." 15 U.S.C. 77m (emphasis added).[5] Section 77m provides the best evidence of Congress's understanding of how constructive-discovery principles apply in the securities context. In a case in which the plaintiff fails to exercise "reasonable

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[5] Unlike Section 10(b), the provisions of law to which Section 77m applies (15 U.S.C. 77k and 77*l*(a)(2)) do not make scienter an element of a statutory violation, but rather make the defendant's lack of knowledge of falsity an affirmative defense. See 15 U.S.C. 77k(b)(3); 15 U.S.C. 77*l*(a)(2).

diligence," Section 77m unambiguously provides that the limitations period begins to run at the time a diligent plaintiff would actually have discovered the defendant's false statement, not at the time (*i.e.*, inquiry notice) when the diligent plaintiff would have commenced an investigation. There is no warrant for construing Section 1658(b)(1), which simply refers to "discovery of the facts constituting the violation" and does not expressly provide that constructive discovery will suffice, to establish an *earlier* trigger for the limitations period.

c. In a case in which even a diligent investigation would take more than two years to complete, the approach that petitioners advocate—under which Section 1658(b)(1)'s limitations period would begin to run when the plaintiff is placed on "inquiry notice" and therefore should commence his investigation—would result in the limitations period expiring before a diligent plaintiff could acquire facts sufficient to survive a motion to dismiss. That result is incompatible with this Court's decision in *Lampf*, which held that the limitations period applicable to private securities actions is not subject to equitable tolling because the period "by its terms, begins after discovery of the facts constituting the violation, making tolling unnecessary." 501 U.S. at 363. That analysis presumes that the two-year limitations period (unlike the five-year "period of repose" that "serve[s] as a cutoff" for all claims, see *ibid.*) cannot bar claims before a reasonably diligent plaintiff could learn the facts necessary to assert them.

In addition to foreclosing the claims of some plaintiffs despite the plaintiffs' exercise of reasonable diligence, petitioners' reading of Section 1658(b)(1) would frustrate the purpose, common to the PSLRA and Section 1658(b), of discouraging so-called "strike suits."

The Senate Report to the Sarbanes-Oxley Act recited that, under *Lampf*, plaintiffs were on a "one year 'stop watch'" that ran "from the moment they know that they have been cheated." S. Rep. No. 146, at 9. In extending the limitations period to two years, the Report explained that "*even after the fraud is discovered*," plaintiffs need additional time to "find out more about exactly who participated in the fraudulent activity and how," in order to "learn[] that an additional wrongdoer" should be "added to the case" that is otherwise ready to be filed. *Ibid.* The report criticized the one-year period as too short, driving plaintiffs "to race into court, so as not to be barred by time," and to "throw[] in every possible defendant and every claim" "almost immediately upon a change in the stock price." *Ibid.* Petitioners' reading of Section 1658(b)(1), under which the two-year limitations period may begin to run well before a reasonably diligent plaintiff learns sufficient facts to support a well-founded complaint, would create renewed incentives to the sort of hasty filings that Congress sought to discourage.[6]

3. Even if the plaintiff fails to undertake a reasonably diligent investigation after inquiry notice, the two-year limitations period runs from when such an investigation would have revealed the "facts constituting the violation," not from when the investigation should have commenced

In the alternative, petitioners urge (Br. 43-48) this Court to adopt a hybrid approach, drawn from decisions

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[6] Petitioners cite the "additional views of eight Senators." See, *e.g.*, Pet. Br. 20, 46. Because seven of those eight Senators voted against extending the statutory period, S. Rep. No. 146, at 22, their views are an unreliable guide for construing Section 1658(b)(1).

of the Second and Third Circuits, see, *e.g.*, *LC Capital Partners, LP* v. *Frontier Ins. Group, Inc.*, 318 F.3d 148, 154 (2d Cir. 2003); *Mathews* v. *Kidder, Peabody & Co.*, 260 F.3d 239, 255 (3d Cir. 2001), under which the time when Section 1658(b)(1)'s two-year limitations period begins to run turns on whether the plaintiff conducted a reasonably diligent investigation. Under petitioners' alternative theory, when a plaintiff diligently investigates his possible claim after being placed on inquiry notice, the two-year period runs from the time the plaintiff actually discovers the "facts constituting the violation." Petitioners contend (Br. 47), however, that "when a plaintiff fails to conduct a reasonably diligent investigation, he can be deemed, as an equitable matter, to have 'discovered' the relevant facts as of the date of inquiry notice," and the two-year period should therefore run from that date. That theory is inconsistent with the text and purposes of Section 1658(b)(1) and with its role in the larger statutory scheme.

a. As explained above (see pp. 16-20, *supra*), constructive "discovery of the facts constituting the violation" is deemed to occur at the time a reasonably diligent investigation would have given the plaintiff actual knowledge of those facts. If that understanding of Section 1658(b)(1) is sound—*i.e.*, if petitioners are wrong in arguing that the plaintiff "discover[s] * * * the facts constituting the violation" when he is placed on inquiry notice—a court has no authority to adopt, even for dilatory plaintiffs, an earlier triggering date for the limitations period than the date Congress specified. Petitioners' fallback theory is in substance an attempt to engraft laches principles onto Section 1658(b)(1); but "[l]aches within the term of the statute of limitations is no defense at law." *United States* v. *Mack*, 295 U.S. 480, 489 (1935).

That is particularly so in the present context, where the five-year period of repose established by Section 1658(b)(2) provides an outer limit on the dilatory plaintiff's ability to pursue securities-law claims. See pp. 24-26, *infra*. Had Congress additionally wished to modify the triggering date for the limitations period in cases in which an investor has been dilatory, Congress could have done so. Here it did not choose to incorporate in this way principles of laches into the statute of limitations it adopted.

Petitioners' alternative theory is also inconsistent with the express constructive-discovery rule established by 15 U.S.C. 77m, which provides that the limitations period should start to run in the relevant cases "after the discovery of the untrue statement or the omission, or after such discovery should have been made by the exercise of reasonable diligence." *Ibid.* Section 77m unambiguously contemplates that, when the plaintiff fails to exercise "reasonable diligence," the limitations period will begin to run when "discovery should have been made," not when the plaintiff should have commenced his investigation. As the best evidence of Congress's intent regarding the operation of constructive-discovery principles in the securities context, Section 77m refutes a reading of Section 1658(b)(1) that would establish an earlier triggering date in cases in which the plaintiff fails to conduct a diligent investigation. See pp. 18-19, *supra*.

b. Petitioners identify (Br. 48-51) three principal policy objections to the government's construction of Section 1658(b)(1), under which the two-year limitations period begins to run at the time that a reasonably diligent investigation would have uncovered the "facts constituting the violation," even if the plaintiff himself fails

to conduct such an investigation. Those objections provide no basis for disregarding the statutory text, and they are unsound even on their own terms.

i. Petitioners contend (Br. 48) that the government's approach "would effectively excuse a plaintiff's failure to conduct a further investigation after being placed on inquiry notice of a Section 10(b) violation" and would place such a plaintiff "in the same position as a plaintiff who does conduct a reasonably diligent investigation." But a plaintiff who conducts a diligent investigation, and who thereby acquires facts sufficient to file a well-grounded complaint, is obviously in a better position than one who fails to obtain such facts, and therefore cannot proceed with his suit (even though he has the same time to do so). Providing the term "discovery" in Section 1658(b)(1) is read to encompass constructive as well as actual discovery, so that a plaintiff cannot extend the period for commencing suit by failing to investigate suspicious circumstances, an investor who is placed on inquiry notice will have an adequate incentive to conduct an investigation.

ii. Petitioners argue (Br. 50) that the government's approach "would lead to potentially grave difficulties in application, because it would force courts to engage in entirely hypothetical inquiries about what a reasonably diligent investigation would have entailed and how long it would have taken for such an investigation to bear fruit." That objection is misguided. To be sure, determining how long a hypothetical investigation would have taken to unearth the "facts constituting the violation" will often involve some approximation. But this lack of complete certainty is an inherent consequence of construing Section 1658(b)(1) to encompass constructive discovery. Although Section 1658(b)(1) might be easier

to apply if its two-year limitations period were triggered only by a plaintiff's *actual* discovery of the relevant facts, petitioners insist (correctly, in our view) that the two-year period may begin to run before actual discovery occurs if "the plaintiff should have known of the relevant facts at an earlier date than he actually did." Br. 18. Petitioners cannot reasonably urge the Court to adopt that interpretation of Section 1658(b)(1) and then complain that the time of constructive discovery is too difficult to ascertain.

iii. Petitioners also contend (Br. 51) that the government's approach "would seemingly render the principle of inquiry notice irrelevant." That is incorrect. To identify the point in time when a reasonably diligent plaintiff would have discovered particular facts, a court must determine both when the plaintiff would have begun his investigation and how long a reasonable investigation would have taken to bear fruit. An approach that disregarded the former question and focused only on how the investigation was conducted once commenced would allow plaintiffs to postpone the triggering of the two-year period simply by declining to begin an investigation. Although the phrase "inquiry notice" does not appear in the statute, it is a convenient shorthand term for the point in time at which the available facts cast sufficient doubt on the propriety of the defendant's conduct that a diligent plaintiff would have begun to investigate. So understood, the concept of "inquiry notice" is integral to Section 1658(b)(1)'s proper application.

c. Petitioners' approach is especially inappropriate where, as here, Congress has adopted a bifurcated limitations period, in which an express "discovery" provision is paired with an absolute period of repose. Cf. *Lampf*, 501 U.S. at 362 n.8 (concluding that "the 1-and-3-year

scheme" contained in then-existing law "represents an indivisible determination by Congress as to the appropriate cutoff point for claims under the statute"). Petitioners rely (*e.g.*, Br. 21-22, 25, 44-45) on such decisions as *Rotella* v. *Wood*, 528 U.S. 549 (2000); *Klehr* v. *A.O. Smith Corp.*, 521 U.S. 179 (1997); and *United States* v. *Kubrick*, 444 U.S. 111 (1979). In each of those cases, the relevant limitations period began to run when the plaintiff's claim "accrued."[7] And in each case, the plaintiff contended that his claim had not "accrued" until he acquired actual or constructive knowledge of some relevant fact. See *Rotella*, 528 U.S. at 552-553; *Klehr*, 521 U.S. at 192; *Kubrick*, 444 U.S. at 118. In rejecting those arguments, the Court expressed concern that adopting the plaintiffs' approach to the "accru[al]" of claims would unduly expand the period of time within which suit could be filed. See *Rotella*, 528 U.S. at 555, 558-559; *Klehr*, 521 U.S. at 192; *Kubrick*, 444 U.S. at 117-118, 123. The Court in *Rotella* noted that "fraud * * * is generally associated with a different accrual rule." 528 U.S. at 557.

Section 1658(b)(1) does not use the term "accrued," but rather specifies the information—*i.e.*, the "facts constituting the violation"—that the plaintiff must (actually or constructively) "discover[]" before the two-year limitations period will begin to run. And unlike the discovery principles that the plaintiffs in the cases discussed

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[7] The statute of limitations at issue in *Rotella* and *Klehr* provided: "Any action * * * shall be forever barred unless commenced within four years after the cause of action accrued." 15 U.S.C. 15b (Clayton Act, applied to civil RICO actions); see *Rotella*, 528 U.S. at 553; *Klehr*, 521 U.S. at 183. The statute of limitations at issue in *Kubrick* barred any claim not brought "within two years after such claim accrues." 28 U.S.C. 2401(b) (Federal Tort Claims Act).

above sought to invoke, Section 1658(b)(1) does not *expand* the period in which suit may be filed. Section 1658(b)(2) establishes a five-year period of repose, and Section 1658(b) requires that suits alleging violations of Section 10(b) must be filed "not later than the earlier of" the dates specified in Subsections (1) and (2). 28 U.S.C. 1658(b). Section 1658(b)(1) therefore can operate only to *shorten* the five-year period (measured from the date of "the violation") set by Section 1658(b)(2), which remains the outer limit for bringing suit. Construing Section 1658(b)(1) in accordance with its terms therefore creates no risk that the time for filing suit will extend indefinitely if the plaintiff is unable (either because of his own dilatory conduct or through circumstances beyond his control) to acquire the information needed to support his claim.

B. Inquiry Notice Of A Possible Section 10(b) Violation Arises Only If Circumstances Suggest A Misrepresentation Or Omission Made With Scienter

Contrary to petitioners' contention (Br. 19-28), an investor is not placed on "inquiry notice" of a potential Section 10(b) claim unless he has reason to suspect that a defendant's possible misrepresentation was made with scienter. Because scienter is an essential element of a Section 10(b) violation, an investor who suspects only an innocent or negligent misrepresentation will have no reason to undertake a potentially time-consuming and costly investigation. Petitioners' rule, especially when combined with their proposal that the two-year period should run from the time of inquiry notice, would create an untoward incentive for plaintiffs to file hastily-drafted complaints, based only on evidence of a misrepresentation, in order to avoid the limitations bar. Plain-

tiffs with meritorious claims, however, would be barred before they could have discovered the violation—and indeed before they would have had reason to *suspect* it.

1. Inquiry notice identifies when a reasonable plaintiff would begin investigating a possible violation

The court of appeals correctly held that, "to trigger 'storm warnings of culpable activity,' in the context of a claim alleging falsely-held opinions or beliefs, investors must have sufficient information to suspect that the defendants engaged in culpable activity, i.e., that they did not hold those opinions or beliefs in earnest." Pet. App. 33a (citation omitted). Two other courts of appeals have likewise held that suspicion of scienter is necessary to trigger inquiry notice. See *Betz*, 519 F.3d at 876, 878; *Sudo Props.*, 503 F.3d at 375, 378 (inquiry notice was not triggered by plaintiff's knowledge that defendant's predictions were "grossly incorrect," until plaintiff "learned for the first time that [defendant] had intentionally misled him"). Other circuits, without expressly addressing the issue, have similarly characterized "inquiry notice" in terms of putting the plaintiff on notice of potential "fraud," which connotes scienter. See *Dodds* v. *CIGNA Sec., Inc.*, 12 F.3d 346, 350 (2d Cir. 1993) (information that "would suggest * * * the probability that [the investor] has been defrauded"), cert. denied, 511 U.S. 1019 (1994); *Maggio* v. *Gerard Freezer & Ice Co.*, 824 F.2d 123, 128 (1st Cir. 1987) (facts that "would have alerted a reasonable investor to the possibility of fraudulent conduct."); *Fujisawa Pharm. Co.* v. *Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997) ("[t]he facts constituting [inquiry] notice must be sufficiently probative of fraud").

Those decisions are consistent with the ultimate statutory inquiry: to identify the point at which a reason-

ably diligent investor should have discovered "the facts constituting *the violation*" of Section 10(b). 28 U.S.C. 1658(b)(1) (emphasis added). As one step in the two-step analysis used to determine when such an investor would have unearthed those facts, the "inquiry notice" concept serves to determine when the investigation should have begun. See pp. 16-18, *supra*. When an investor has reason to suspect that he was given inaccurate securities-related information, but has no reasonable basis to suppose that the misstatement was anything other than an error, he has no cause to think that a securities violation has occurred. Under those circumstances, a reasonable investor would not commence an investigation: he would not devote time or resources to exploring a potential legal action for which an essential element appears to be lacking.

2. Suspicion of scienter is necessary for inquiry notice, though it may arise from suspicion of falsity

Petitioners contend (Pet. Br. 21-22, 41-42) that inquiry notice can exist without suspicion of scienter because scienter is not one of the "core" facts constituting a securities-fraud violation. That is incorrect. As discussed above, see p. 12, *supra*, this Court has repeatedly held that scienter is an element of a Section 10(b) violation. See, *e.g.*, *Aaron*, 446 U.S. at 691. Congress confirmed the centrality of scienter to a Section 10(b) violation in the PSLRA's requirement that a securities-fraud complaint allege facts giving rise to a "strong inference" of scienter. See 15 U.S.C. 78u-4(b)(1) and (2). And because Section 1658(b)(1) applies only to "claim[s] of fraud, deceit, manipulation, or contrivance," 28 U.S.C. 1658(b), the limitations provision itself confirms the cen-

trality of scienter to the violations it covers. See p. 12, *supra*.

Petitioner's reliance (Br. 21-22) on *TRW Inc.* v. *Andrews*, 534 U.S. 19, 30 (2001), is misplaced. In *TRW*, the Court held that "Congress implicitly excluded [from the Fair Credit Reporting Act, 15 U.S.C. 1681p,] a general discovery rule by explicitly including a more limited one." *TRW*, 534 U.S. at 28. In the course of its analysis, the Court observed that, "[i]f [a] consumer habitually paid her bills on time," a denial of her credit application "might well lead her to suspect a prior credit agency error," thereby placing her on "inquiry notice" so long as "a reasonable person in her position would have learned of the injury in the exercise of due diligence." *Id.* at 30. The decision in *TRW* does not suggest that a potential plaintiff can be placed on "inquiry notice" even though she has no reason to suspect that a statutory violation has occurred. Rather, the Court simply recognized that the requisite suspicion may be based on reasonable inferences from the totality of the circumstances (*e.g.*, an unexplained denial of credit to an applicant who has "habitually paid her bills on time") even in the absence of direct evidence of the defendant's wrongdoing.

Similarly in the securities-fraud context, circumstances may often arise in which an innocent mistake is inherently unlikely, so that information giving rise to a suspicion of falsehood will itself give rise to a suspicion of fraud. In particular, when a "representation is false for reasons likely to have been within the knowledge of the company when making it, investors upon learning of the falsity should smell the possibility of fraud." *Law* v. *Medco Research, Inc.*, 113 F.3d 781,785 (7th Cir. 1997) (Posner, J.); see, *e.g.*, *Mathews*, 260 F.3d at 252-255; *Cooperativa de Ahorro y Credito Aguada* v. *Kidder, Pea-*

body & Co., 129 F.3d 222, 224 (1st Cir. 1997). But that is not necessarily the case when the inaccurate statement concerns information that is external to the declarant—such as information about "a customer, supplier, licensee, licensor, or other outsider"—or events that might "have arisen after the representation was made." *Law*, 113 F.3d at 785. In the latter case, such as when a prediction about the future does not come to pass, facts demonstrating the original statement to have been inaccurate will not necessarily suggest that the statement was fraudulent when made.[8]

C. Section 1658(b)(1) Does Not Bar Respondents' Claims

1. The court of appeals correctly held that the FDA Warning Letter did not put respondents on "inquiry notice" of possible securities fraud because that letter did not suggest that Merck had made knowing misstatements about the safety of Vioxx. The FDA Warning Letter charged Merck with promotional activities for the medicine that were "false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act." J.A. 339. The FDA determined that Merck had "selectively present[ed]" the naproxen hypothesis while "fail[ing] to disclose that [the] explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have prothrombotic properties." J.A. 340.

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[8] The fact that information was within a defendant's control will not necessarily lead a reasonable investor to suspect scienter; inquiry notice depends on the circumstances of each case. See *Dodds*, 12 F.3d at 350; *Mathews*, 260 F.3d at 251. For example, an accounting restatement would not automatically give rise to inquiry notice.

In making those criticisms, the FDA did not conclude that the naproxen hypothesis was untrue or even unlikely, or that Merck did not believe in it. Rather, the FDA recognized the naproxen hypothesis as "a possible explanation" for the known data, but faulted Merck for emphasizing that theory while ignoring the alternative —that Vioxx increased the risk of heart attack. J.A. 340. Such slanted or incomplete discussions of the pertinent medical evidence, when directed at doctors who must decide whether to prescribe a drug, is of great concern to the FDA. An issuer of securities, however, does not engage in fraud or deceit by failing to give equal attention to a competing theory in all its public utterances simply because the issuer's explanation ultimately turns out to be wrong. And because the public record already showed that there were competing explanations of the available data and that neither had been substantiated, J.A. 291-292, the FDA's admonition that the naproxen hypothesis remained unproven provided respondents with no additional information bearing on their investment decisions.

2. Even if the FDA letter had placed respondents on "inquiry notice," their current claims would still be timely. As explained above, constructive "discovery of the facts constituting the violation," 28 U.S.C. 1658(b)(1), is deemed to occur at the time when a reasonably diligent investor would have unearthed facts establishing each element of a statutory violation with sufficient specificity to file an adequate complaint—not when the investor would have started investigating. Even assuming that the FDA letter would have led a reasonably diligent investor to suspect that Merck did not actually believe the naproxen hypothesis, petitioners identify no means by which respondents could have con-

firmed that suspicion by an independent inquiry. The only apparent ways for an investor to ascertain whether petitioners' expression of confidence in the naproxen hypothesis was genuinely held would be to gain access to internal corporate documents or to conduct a scientific study of Vioxx to determine whether Merck could possibly believe what it was saying. An investor need not display the skills of a private detective or research chemist, however, in order to exercise reasonable diligence in investigating and pursuing possible securities-fraud claims. And "[i]t is obviously unreasonable to charge the plaintiff with failure to search for the missing element of the cause of action if such element would not have been revealed by such search." *TRW*, 534 U.S. at 30 (citing 2 Calvin Corman, *Limitation of Actions* § 11.1.6, at 164 (1991)).

Indeed, even the district court, which held that respondents' claims were barred by Section 1658(b)(1), did not suggest that respondents could have discovered facts constituting a securities violation by November 6, 2001—*i.e.*, two years before the complaint was filed on November 6, 2003. Rather, the court stated (without meaningful explanation) that "a reasonable investor would have discovered the basis for his fraud claims against Merck with respect to alleged misrepresentations about VIOXX within *the two years following* the storm warnings" that the court determined arose by October 9, 2001. Pet. App. 85a, 98a (emphasis added). Even if that assessment were well-founded, it would provide no basis for concluding that respondents should have had "discovery of the facts constituting the violation" by November 6, 2001, less than a month after the "storm warnings" arose.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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AMICUS CURIAE BRIEF

No. 08-905

IN THE

Supreme Court of the United States

MERCK & CO., INC., *et al.*,

Petitioners,

v.

RICHARD REYNOLDS, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF AMICI CURIAE AARP AND DETECTIVES' ENDOWMENT ASSOCIATION ANNUITY FUND IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICI CURIAE [1]

AARP is a non-partisan, non-profit organization with nearly 40 million members, working and retired, dedicated to addressing the needs and interests of people aged 50 and older. Through education, advocacy, and service, and by promoting independence, dignity, and purpose, AARP seeks to enhance the quality of life for all. As one method of promoting independence, AARP attempts to foster the economic security of individuals as they age by seeking to increase the availability, security, equity, and adequacy of public and private retirement plans. In this regard, AARP has a longstanding interest in the operation of the securities markets because of the critical role they play in helping ensure financial security in retirement. A considerable amount of AARP's work in this area has focused on combating fraudulent practices in the nation's securities industry due to the fact that older people are frequent victims of such fraud. AARP has regularly commented on legislative and regulatory proposals that address investment fraud and opposed efforts to limit the remedies available to defrauded investors.

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1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae, their members, or their counsel made a monetary contribution to its preparation or submission. The parties have filed blanket waivers consenting to the filing of this brief. *Amici curiae* are grateful for the assistance of Heather V. Lynch and Matthew M. Gerend in preparing the brief.

The Detectives' Endowment Association Annuity Fund is a retirement fund for the benefit of over 9,100 active and retired New York City Police Department detectives. The total value of assets available through the Fund was over $140 million as of December 2008. A significant portion of the Fund's assets are invested in the equity capital markets.

SUMMARY OF ARGUMENT

This Court has "stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there." *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). "When the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'" *Id.* at 254 (quoting *Rubin v. United States*, 449 U.S. 424, 430 (1981)); *see Arthur Andersen LLP v. Carlisle*, 129 S. Ct. 1896, 1903 n.6 (2009) ("It is not our role to conform an unambiguous statute to what we think 'Congress probably intended.'").

Section 1658(b) of Title 28 of the United States Code states:

> .... a private right of action that involves a claim of [securities] fraud ... may be brought not later than the earlier of—
>
> (1) 2 years *after the discovery of the facts constituting the violation*; or
>
> (2) 5 years after such violation.

28 U.S.C. § 1658(b) (emphasis added). The phrase "the discovery of the facts constituting the violation" raises two questions: *First*, what is "discovery"? *Second*, what are "the facts constituting the violation"?

"Discovery" requires an investor to have actual knowledge of the facts he has discovered. Discovery does not mean "should have discovered," much less "should have discovered after an investigation." Indeed, when Congress wants to have a limitation period start upon constructive discovery, it says so. For example, Section 13 of the Securities Act of 1933 states: "No action shall be maintained . . . unless brought within one year after *the discovery* of the untrue statement or the omission, *or after such discovery should have been made by the exercise of reasonable diligence*." 15 U.S.C. § 77m (emphasis added).

The phrase "facts constituting the violation" also has a plain meaning. 28 U.S.C. § 1658(b). It is "naturally understood to refer to facts that, if pleaded in a securities-fraud complaint, would be sufficient to survive a motion to dismiss." Brief for the United States as Amicus Curiae Supporting the Respondent, *Trainer Wortham & Co. v. Betz*, 129 S. Ct. 339 (2008) (No. 07-1489), 2009 WL 1090416, at *8 (April 20, 2009) ("U.S. Br."). Thus, if an investor has discovered no facts to support an essential element of the securities fraud claim, such as materiality or scienter, the investor has not discovered the facts "constituting" the violation.

Moreover, the phrase "facts constituting" has a specific historical meaning. Section 1658(b) is based on Section 9(e) of the Securities Exchange Act of 1934, which states: "No action shall be maintained . . . unless brought within one year after the discovery of the facts constituting the violation and within three years after such violation." 15 U.S.C. § 78i(e). Congress enacted this statute in 1934 – four years before the Federal Rules of Civil Procedure became effective and during the time when the New York Code of 1848, or "Field Code," was in regular use.

The phrase "facts constituting" is based on the Field Code's requirement of what a litigant had to plead in his initial filing or "declaration." To begin a lawsuit, a plaintiff had to include "[a] statement of the *facts constituting* the cause of action. . . ." 1848 N.Y. Field Code Laws ch. 379, § 142, amended by ch. 438 (1949) (emphasis added). Thus, the historical meaning of "facts constituting the violation" refers to when, in today's parlance, an investor can state his claim. Disregarding the text of the statute, the lower courts have imposed a requirement of "inquiry notice," which imposes an extraordinary burden on ordinary investors such as those represented by the *amici curiae*.

Amici curiae respectfully submit that this Court should enforce the statute as it is written: The two-year limitation should start when investors discover (i.e., have actual knowledge of) the facts constituting the violation (i.e., facts that state a claim).

ARGUMENT

I. Background on Section 1658(b)

"In the wake of the 1929 stock market crash and in response to reports of widespread abuses in the securities industry, the 73d Congress enacted two landmark pieces of securities legislation: the Securities Act of 1933 (1933 Act) and the Securities Exchange Act of 1934 (1934 Act)." *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 170-71 (1994). Generally speaking, the 1933 Act regulates the offering and sale of securities in the initial markets, and the 1934 Act regulates the buying and selling of these

securities in the aftermarkets (e.g., New York Stock Exchange). *See id.* at 171.

Both Acts explicitly provide investors with private rights of action that have statutes of limitations. *Id.* For example, the 1933 Act contains two provisions, Sections 11 and 12, which allow purchasers to sue when alleging injury from material misstatements or omissions in registration statements or prospectuses. 15 U.S.C. §§ 77k-l. Section 13 limits the time an investor has to bring these claims. 15 U.S.C. § 77m.

Likewise, Section 9 of the 1934 Act prohibits the manipulation of security prices, 15 U.S.C. §§ 78i(a)-(d), and explicitly allows investors to sue. 15 U.S.C. § 78i(e). The time an investor has to bring a Section 9 claim is limited by Section 9(e). 15 U.S.C. § 78i(e). Section 9(e) has a "two-tiered" structure composed of a one-year limitation period triggered by "discovery of the facts constituting the violation" and a three-year period of repose triggered by the violation. *Id.* The three-year period of repose may cut off the one-year limitation triggered by discovery. For example, if the plaintiff discovers the facts constituting the violation two months prior to the expiration of the three-year repose period, then the plaintiff has two months, not one year, to bring the claim.

A major difference between the time limitations set by Section 13 of the 1933 Act and Section 9(e) of the 1934 Act is that Section 13 states that the limitation period commences "after the discovery of the untrue statement or the omission, *or after such discovery should have been made by the exercise of reasonable*

diligence . . . ." 15 U.S.C. § 77m (emphasis added). In contrast, Section 9(e) states that the limitation period starts "after the discovery of the facts constituting the violation." 15 U.S.C. § 78i(e).

Section 10(b) of the 1934 Act empowers the Securities and Exchange Commission ("SEC") to make regulations prohibiting deceptive practices in the buying and selling of securities. 15 U.S.C. § 78j(b). In 1942, the SEC promulgated Rule 10b-5. 7 Fed. Reg. 3804 (May 22, 1942) (Exchange Act Release No. 3230). Among other things, Rule 10b-5 states "[i]t shall be unlawful for any person, directly or indirectly . . . [t]o make any untrue statement of a material fact . . . in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5.

In 1946, for the first time, a court held that investors could bring a private action for violations of Rule 10b-5. *Kardon v. Nat'l Gypsum Co.*, 69 F. Supp. 512, 513-14 (E.D. Pa. 1946). This holding has been repeatedly affirmed. *Herman & MacLean v. Huddleston*, 459 U.S. 375, 380 (1983) (explaining that the implied private right of action under Rule 10b-5 is "simply beyond peradventure"). "Though the text of the Securities Exchange Act does not provide for a private cause of action for § 10(b) violations, the Court has found a right of action implied in the words of the statute and its implementing regulation." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 128 S. Ct. 761, 768 (2008) (citing *Superintendent of Ins. of N.Y. v. Bankers Life & Casualty Co.*, 404 U.S. 6, 13 n.9 (1971)).

In 1991, this Court resolved which statute of limitations applies to claims brought under Rule 10b-5

by holding that "where, as here, the claim asserted is one implied under a statute that also contains an express cause of action with its own time limitation, a court should look first to the statute of origin to ascertain the proper limitations period." *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350, 359 (1991). Although fully aware of the textual differences between Section 13 of the 1933 Act and Section 9(e) of the 1934 Act, this Court "select[ed] as the governing standard for an action under § 10(b) the language of § 9(e) of the 1934 Act, 15 U.S.C. § 78i(e)." *Id.* at 364 n.9.

Several years after this Court's decision in *Lampf*, a massive number of frauds were revealed throughout the financial markets. "During the 1990s, earnings restatements, long recognized as a proxy for fraud, suddenly soared." John C. Coffee, Jr., *What Caused Enron? A Capsule Social and Economic History of the 1990s*, 89 CORNELL L. REV. 269, 282 (2004). From 1997 to 2002, approximately ten percent of all companies listed on the New York Stock Exchange or NASDAQ announced at least one earnings restatement. U.S. Gen. Accounting Office, GAO-138: FINANCIAL STATEMENT RESTATEMENTS: TRENDS, MARKET IMPACTS, REGULATORY RESPONSES, AND REMAINING CHALLENGES 26 (2002), *available at* http://www.gao.gov/new.items/d03138.pdf.

The fraud often went back years. For example, on November 8, 2001, Enron announced it had overstated earnings by a stunning $586 million since 1997. ACCOUNTING REFORM AND INVESTOR PROTECTION: HEARINGS BEFORE THE SENATE COMM. ON BANKING, HOUSING, AND URBAN AFFAIRS, Volume I, 107th Cong. 1 (2002). The restatements to Enron's financial statements resulted

in a net income reduction of $1.5 billion, and the company declared bankruptcy on December 2, 2001. *Id.* Enron investors lost more than $60 billion, while 5,000 Enron employees lost their jobs and retirement savings. ARTHUR LEVITT, TAKE ON THE STREET 150-52 (First Vintage Books ed., Vintage Books 2003).

Congress responded by passing the Sarbanes-Oxley Act of 2002. Pub. L. No. 107-204, 116 Stat. 745 (2002). Section 804 of the Act is entitled "Statute of Limitations for Securities Fraud." It states in full:

> (a) IN GENERAL. — Section 1658 of title 28, United States Code, is amended —
>
> (1) by inserting "(a)" before "Except"; and
>
> (2) by adding at the end the following:
>
> "(b) Notwithstanding subsection (a), a private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws, as defined in section 3(a)(47) of the Securities Exchange Act of 1934 (15 U.S.C. 78c(a)(47)), may be brought not later than the earlier of—
>
> "(1) 2 years after *the discovery of the facts constituting the violation*; or

"(2) 5 years after such violation."

Pub. L. No. 107-204, § 804 (emphasis added).[2]

II. "Discovery of the Facts Constituting the Violation" Has a Plain Meaning

A. Discovery Requires Actual Knowledge

Section 1658(b) of Title 28 of the United States Code states that an investor may not bring a claim of securities fraud two years after "*the discovery of the facts constituting the violation.*" 28 U.S.C. § 1658(b) (emphasis added). Section 1658(b) supersedes Section 9(e) of the 1934 Act, 15 U.S.C. § 78i(e), the statute of limitations that this Court held applied to claims brought under Rule 10b-5 in *Lampf*, 501 U.S. at 364. The phrase "discovery of the facts constituting the violation" is found in both Section 1658(b) and Section 9(e).[3] The main difference is that Section 1658(b) extends the limitation period after discovery from one to two years, and the repose period after the violation from three to five years.

Lower courts have acknowledged that the phrase "discovery of the facts constituting the violation" when

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2. Enacted in 1990, 28 U.S.C. § 1658 is a general statute of limitations that applies to all subsequently enacted federal statutes that do not have express limitations periods.

3. Because Section 9 is a "rarely used remedy," *Lampf*, 501 U.S. at 376 (Kennedy, J., dissenting), there are no reported opinions interpreting the discovery standard for Section 9(e) as applied to Section 9 claims. Rather, opinions interpreting Section 9(e) involve Rule 10b-5 claims filed by investors before Congress enacted section 1658(b).

"read literally, requires actual knowledge to set the statute of limitations running." *Tregenza v. Great Am. Communications Co.*, 12 F.3d 717, 721 (7th Cir. 1993).[4] Commentators agree: "The precise words of the statute would seem to indicate that the [time limitation] commences when the plaintiff actually discovers the violation." Lewis D. Lowenfels & Alan R. Bromberg, *SEC Rule 10b-5 and Its New Statute of Limitations: The Circuits Defy the Supreme Court*, 51 BUS. LAW. 309, 312 (1996). "[T]he precise language of the statute—within one year after discovery of the facts constituting the violation—is clear. There is neither ambiguity nor equivocation." *Id.* at 333.[5]

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4. *See Gruber v. Price Waterhouse*, 911 F.2d 960, 964 n.4 (3d Cir. 1990) (explaining that a previous case "actually relied upon the Securities Exchange Act of 1934 which does not provide for inquiry notice"); *In re Enron Corp. Sec., Derivative & ERISA Litig.*, No. 01 Civ. 3624, 2004 WL 405886, at *8 (S.D. Tex. Feb. 25, 2004) ("The language of section 9(e) . . . suggests that the one-year period requires actual discovery to trigger limitations . . . . section 9 does not appear to trigger limitations when the plaintiff 'should have' discovered the wrongdoing."); *Werner v. Satterlee, Stephens, Burke & Burke*, 797 F. Supp. 1196, 1204 (S.D.N.Y. 1992) (stating that "I understand the [statute of limitations] to run from a plaintiff's actual discovery of fraud, whether or not he should have discovered it earlier."); *Hauman v. Illinois Power Co.*, No. 89-1130, 1991 WL 354887, at *8 (C.D. Ill. Aug. 29, 1991) (stating that "it seems clear that the statute of limitations adopted by the Supreme Court for actions under § 10(b) begins to run only upon actual discovery of the facts constituting the fraud, not when the Plaintiffs want inquiry notice.").

5 *See* Charles Benjamin Nutley, Comment, *Triggering One-Year Limitations on Section 10(b) and Rule 10b-5 Actions: Actual or Inquiry Discovery?*, 30 SAN DIEGO L. REV. 917, 950 (1993) (Cont'd)

Section 1658(b) should be read literally. The ordinary meaning of "discovery" requires actual knowledge. Discovery does not mean, as Petitioner has written, "when the plaintiff should have known of the relevant facts, even if he did not actually know of those facts until a later date." Brief for the Petitioner at 13, Merck & Co., Inc. v. Reynolds, No. 08-905 (Apr. 7, 2009). Indeed, it is impossible to "discover" facts but "not actually know of those facts until a later date." *Id.* "The language is straightforward, and with a straightforward application ready to hand, statutory interpretation has no business getting metaphysical." *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 37 (1998).

Moreover, Congress knew how to impose constructive discovery "when it chose to do so." *Cent. Bank*, 511 U.S. at 176 (interpreting Section 10(b) in light of a statute enacted twenty-five years earlier). For example, Section 13 of the 1933 Act – enacted one year before Section 9(e) of the 1934 Act – states in full:

> No action shall be maintained to enforce any liability created under section 77k or 77l(a)(2) of this title unless brought within one year after the discovery of the untrue statement

---

(Cont'd)

("Holding that only actual notice triggers the one-year limitation, on the other hand, is a proper exercise of statutory construction principles; it acknowledges the statutory distinctions, and gives effect to the *Lampf* language selecting section 9(e) and distinguishing it from other sections.").

> or the omission, *or after such discovery should have been made by the exercise of reasonable diligence*, or, if the action is to enforce a liability created under section 77l(a)(1) of this title, unless brought within one year after the violation upon which it is based. In no event shall any such action be brought to enforce a liability created under section 77k or 77l(a)(1) of this title more than three years after the security was bona fide offered to the public, or under section 77l(a)(2) of this title more than three years after the sale.

15 U.S.C. § 77m (emphasis added). If this Court interprets "discovery" to mean "should have discovered," the phrase "after such discovery should have been made by the exercise of reasonable diligence" will be "as surplusage—as words of no consequence." *Ratzlaf v. United States*, 510 U.S. 135, 140 (1994).[6]

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6. *See also* Lowenfels & Bromberg, *SEC Rule 10b-5 and Its New Statute of Limitations*, 51 BUS. LAW. at 333-34 ("Indeed, when Congress wanted to insert an 'inquiry notice' trigger it did so specifically in Securities Act section 13."). *Cf. Pennsylvania Dept. of Public Welfare v. Davenport*, 495 U.S. 552, 562 (1990) ("Our cases express a deep reluctance to interpret a statutory provision so as to render superfluous other provisions in the same enactment."); *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 837 (1988) ("As our cases have noted in the past, we are hesitant to adopt an interpretation of a congressional enactment which renders superfluous another portion of that same law.") (collecting cases).

Any doubt on what "discovery" means is dispelled by this Court's decision in *Lampf*. As commentators have argued:

> [T]he decision of the Supreme Court in *Lampf* is clear . . . there is neither ambiguity nor equivocation. The Court had the contrasting language of Securities Act section 13 before it; it quoted Securities Act section 13 side-by-side with Exchange Act section 9(e) in successive footnotes. The court acknowledged that "the various 1- and-3-year periods contained in the 1934 and 1933 Acts differ slightly in terminology" and then specifically and precisely emphasized " to the extent that these distinctions in the future might prove significant, we select as the governing standard for an action under § 10(b) the language of § 9(e) of the 1934 Act . . . ."

Lowenfels & Bromberg, *SEC Rule 10b-5 and Its New Statute of Limitations*, 51 BUS. LAW at 334. Indeed, the majority in *Lampf* rejected the dissent's argument that the Court should "remand with instructions that a § 10(b) action may be brought at any time within one year after an investor discovered *or should have discovered a violation*." *Lampf*, 501 U.S. at 379 (Kennedy, J., dissenting) (emphasis added).

"The intention of the legislature is to be collected from the words they employ. Where there is no ambiguity in the words, there is no room for construction." *United States v. Wiltberger*, 18 U.S. 76, 95-96 (1820) (Marshall, C.J.). "Where the language is

plain and admits of no more than one meaning, the duty of interpretation does not arise, and the rules which are to aid doubtful meanings need no discussion." *Caminetti v. United States*, 242 U.S. 470, 485 (1917); *see Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998) ("[I]t is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed.").

Section 1658(b) states that the two-year statute of limitations begins upon the "discovery" of the facts constituting the violation. "Discovery" does not mean "should have discovered," nor can it, given this Court's "duty to refrain from reading a phrase into the statute when Congress has left it out." *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993).[7] "Discovery" should be

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7. *See United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 490 (2001) (refusing to "read into" the Controlled Substances Act a medical necessity defense available at common law); *Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 15-16 (2001) (refusing to "read an 'Indian trust' exemption into" the Freedom of Information Act when there was "simply no support for the exemption in the statutory text"); *U.S. Dep't of Justice v. Tax Analysts*, 492 U.S. 136, 154 (1989) (refusing to "read into" the Freedom of Information Act "a disclosure exemption that Congress did not itself provide"); *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 836-37 (1988) (refusing to "read into" ERISA § 514(a) a limitation expressly included in another ERISA provision); *Burlington N. R.R. Co. v. Bhd. of Maint. of Way Employees*, 481 U.S. 429, 447 (1987) (refusing to "read . . . into the silence of" the Railway Labor Act a limitation on union self-help that existed at the time the Act became law); *United States v. Pennsylvania Indus. Chem. Corp.*, 411 U.S. 655, 663-64 (1973) (refusing to "read into" § 13 of the Rivers and Harbors Act of 1899 a provision found elsewhere in that Act and in the Rivers and Harbors Act of 1905).

interpreted according to its plain meaning and require actual knowledge of the facts constituting the violation.

B. "Facts Constituting the Violation" Requires a Plaintiff to Be Able To State a Claim

The debate over how to interpret "discovery" has overshadowed a more fundamental question that this Court must also answer: discovery of what? Section 1658(b) states that the two-year limitation period does not begin to run until "the discovery of *the facts constituting the violation.*" 28 U.S.C § 1658(b) (emphasis added). As the United States has argued: "The phrase 'facts constituting the violation' is naturally understood to refer to facts that, if pleaded in a securities-fraud complaint, would be sufficient to survive a motion to dismiss." U.S. Br. at 9.

A "violation" occurs when a person breaks a law. *See Johnson v. Aljian*, 490 F.3d 778, 781 (9th Cir. 2007) (quoting BLACK'S LAW DICTIONARY 1408 (5th ed. 1979), which states "violation" means "[i]njury; infringement; breach of right, duty, or law"). "When, for example, someone asks if a person 'violated' the speeding law, she is ordinarily understood as inquiring whether that person disregarded the posted speed limit . . . ." *Id.*

Likewise, Rule 10b-5 prohibits, among other things, a person from making "any untrue statement of a material fact . . . . in connection with the purchase or sale of any security." 17 CFR § 240.10b-5. In *Ernst & Ernst v. Hochfelder*, 425 U.S. 185 (1976), this Court held that, because the SEC passed Rule 10b-5 under authority granted by Section 10(b) of the 1934 Act,

15 U.S.C. § 78j, a defendant must make the untrue statement with "scienter" – that is, "a mental state embracing intent to deceive, manipulate, or defraud." 425 U.S. at 193 n.12.

Thus, "[i]n a typical § 10(b) private action a plaintiff must prove (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 128 S. Ct. 761, 768 (2008). A "violation" occurs when a person's conduct involves each of these elements and, if one of these elements is missing, a violation has not occurred.

The two-year limitation period does not begin until a plaintiff discovers the "facts constituting" the violation. Constituting means to form, compose, or make up. If the investor has not discovered any facts that support an element – such as scienter or materiality – the two-year statute of limitations cannot begin to run because the investor has not discovered "the facts constituting the violation." 28 U.S.C. § 1658(b).[8] In other words, the two-year statute of limitations cannot apply until the investor discovers that the law has been violated.

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8. *Cf. United States v. Int'l Minerals & Chem. Corp.*, 402 U.S. 558 (1971) ("knowingly" means knowledge of facts constituting a violation, not actual knowledge of regulations).

This interpretation is consistent with how courts interpret "constituting," and even "facts constituting," in other contexts. Rule 9(b) of the Federal Rules of Civil Procedure requires a plaintiff alleging fraud to state with particularity "the circumstances *constituting* fraud or mistake." Fed. R. Civ. P. 9(b) (emphasis added). Courts have repeatedly interpreted this phrase to "mean[] the who, what, when, where, and how" of the alleged fraud. *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990). Thus, courts will dismiss complaints by plaintiffs if they can not satisfy one of these requirements, because such claims have failed to plead the circumstances *constituting* the fraud. *See, e.g., Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 874 (5th Cir. 2008) ("[Plaintiff] has failed to meet several of the Rule 9(b) requirements: 'what' statements were in the budget, 'who' prepared it, and 'how' it was used to get government funds.").

Likewise, Rule 7(c) of the Federal Rules of Criminal Procedure requires that an indictment contain "the essential *facts constituting* the offense charged." Fed. R. Crim. P. 7(c)(1) (emphasis added); *see also Russell v. United States*, 369 U.S. 749, 762 (1962). If an indictment is missing facts that support an element of an offense charged, it does not satisfy Rule 7(c). *See Russell*, 369 U.S. at 762; *see also United States v. Pirro*, 212 F.3d 86, 93 (2d Cir. 2000) ("[T]he indictment must state some fact specific enough to describe a particular criminal act, rather than a type of crime. The indictment failed to sufficiently allege the second element of a section 7206(1) violation, namely a material falsehood or an omission that amounted to a material falsehood.").

The interpretation of "facts constituting the violation" is also consistent with the phrase's historical meaning. *See Keene Corp. v. United States*, 508 U.S. 200, 210 (1993) (turning "to earlier readings of the word 'claim' as it appears in this statute"). Section 1658(b) is based on Section 9(e) of the Securities Exchange Act of 1934, which states: "No action shall be maintained . . . unless brought within one year after the discovery of the facts constituting the violation and within three years after such violation." 15 U.S.C. § 78i(e). Congress enacted this statute in 1934 – four years before the Federal Rules of Civil Procedure became effective and while the New York Code of 1848, or "Field Code," was in regular use.[9]

The phrase "facts constituting" is based on the Field Code's requirement of what a litigant had to plead in his initial filing or "declaration." To begin a lawsuit, a plaintiff had to include "[a] statement of the *facts constituting* the cause of action." *Id.*; *Charles E. Clark, The Complaint in Code Pleading*, 35 YALE L.J. 259, 285 (1926) ("One of the most important changes of the New York Code of Pleading and Practice of 1848, so at least the code makers believed, was to be found in the requirement that there should be stated 'in ordinary and concise language' the *facts* constituting each cause of action or defense.") (emphasis in original).

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9. *See* Order of Dec. 20, 1937, 302 U.S. 783, 783 (1937) (promulgating the Rules "pursuant to Section 2" of the Rules Enabling Act); An Act to Simplify and Abridge the Practice, Pleadings and Proceedings of the Courts of this State (Code of Procedure), 1848 N.Y. Laws 497; *see generally* Charles E. Clark, *Handbook of the Law of Code Pleading* 21-31 (2d ed. 1947) (discussing the history of the Field Code).

Thus, the phrase's most natural meaning is the same as its historical meaning, and consistent with how courts interpret Rule 9(b) of the Federal Rules of Civil Procedure and Rule 7(c) of the Federal Rules of Criminal Procedure. The two-year statute of limitations does not begin until the investor has discovered facts that, if pleaded in a complaint, would state a claim and survive a motion to dismiss.

III. Interpreting Section 1658(b) According to Its Plain Meaning Does Not Produce an Absurd Result

"It is well established that 'when the statute's language is plain, the sole function of the courts-at least where the disposition required by the text is not absurd-is to enforce it according to its terms.'" *Lamie v. U.S. Trustee*, 540 U.S. 526, 534 (2004) (quoting *Hartford Underwriters Ins. Co. v. Union Planters Bank, N. A.*, 530 U.S. 1, 6 (2000)). Thus, this Court has refused to apply the plain language of a statute if it leads to "bizarre" results. *United States v. Brown*, 333 U.S. 18, 27 (1948).

> For example, if a reading of a statute would render another section within the statute or within the act inoperative or contradictory, then the court will try to read the statute as a whole to make sense. *See, e.g., Yates v. Hendon*, 541 U.S. 1, 17-18 (2004) (avoiding "absurd results" by refusing to adopt a reading of ERISA that would result in "intolerable conflict" between separate titles of the Act) (citation omitted); *Barnhart v.*

> *Sigmon Coal Co.*, 534 U.S. 438, 461-62 (2002) (declining to invoke an exception to the plain language rule because the plain language of the statute did not contain "conflicting provisions"); *Brown*, 333 U.S. at 25-27 (refusing to give effect to the plain language of the statute when doing so would render the statute unenforceable as to many potential offenders).

Amalgamated Transit Union Local 1309, AFLCIO v. Laidlaw Transit Servs., Inc., 448 F.3d 1092, 1098 (9th Cir. 2006) (Bybee, J., dissenting from the denial of rehearing *en banc*); *see generally* John F. Manning, *The Absurdity Doctrine*, 116 HARV. L. REV. 2387 (2003).

Petitioner has not argued that it is absurd, bizarre, or contradictory to interpret Section 1658(b) so that the two-year statute of limitations does not start until investors have discovered facts that allow them to file a complaint.[10] Rather, Petitioner, and *amici curiae* in support of Petitioner, make various policy arguments to justify their various positions. "The short answer is

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10. In fact, at one point in its brief, Petitioner appears to endorse the position taken by *amici curiae* by stating: "Under the correct legal standard, respondents were on inquiry notice of their claim more than two years before the initial version of the complaint was filed, because *they possessed considerable information suggesting the possibility that petitioners had engaged in securities fraud* in connection with their statements concerning Vioxx." Brief for the Petitioner at 14, *Merck*, 129 S. Ct. 2432 (2009) (No. 08-905) (emphasis added). If "the possibility of fraud" is sufficient to support a complaint (prior to discovery), then Petitioner and *amici curiae* are in agreement.

that Congress did not write the statute that way." *United States v. Naftalin*, 441 U.S. 768, 773-74 (1979). "Whatever merits these and other policy arguments may have, it is not the province of [the courts] to rewrite the statute to accommodate them." *Artuz v. Bennett*, 531 U.S. 4, 10 (2000).

The fact is that it is entirely reasonable for Congress to enact a statute that requires actual discovery, as opposed to "inquiry notice," before the two-year statute of limitations starts. An actual discovery standard provides courts with a bright-line rule to apply, as the only question to answer is when did the plaintiff actually discover the facts constituting the violation. In contrast, "[w]hat information raises sufficient 'red flags' to put shareholders on inquiry notice is . . . not answerable as a *per* se matter." *Berry v. Valance Tech, Inc.*, 175 F.3d 699, 704 n.6 (9th Cir. 1999). It is hardly "absurd" or "bizarre" for Congress to have a preference for rules over standards. *Cf.* Antonin Scalia, *The Rule of Law as a Law of Rules*, 56 U. CHI. L. REV. 1175, 1178-80 (1989). Moreover, actual discovery also avoids "forc[ing] shareholders to choose between 'risking what may be a frivolous suit filed timely on skimpy facts, and spending time investigating further on the chance that the short fuse may be running and later bar a legitimate action.'" *Id.* (quoting Charles Benjamin Nutley, *Triggering One-Year Limitations on Section 10(b) and Rule 10b-5 Actions: Actual or Inquiry Discovery?* 30 SAN DIEGO L. REV. 917, 948 (1993)).

In addition, Congress had good reasons to give investors two years starting from the time they discover facts constituting the violation to file a complaint. The

two-year period under Section 1658(b) gives investors time to investigate the scope of the fraud, and therefore, whether "an additional wrongdoer or theory should be added to the case . . . ." S. Rep. No. 107-146, at 9 (2002). The additional time is needed because:

> Especially in securities fraud cases, the complexities of how the fraud was executed often take well over a year to unravel, even after the fraud is discovered. Even with use of the full resources of the FBI, a Special Task Force of Justice Department Attorneys, and the power of a federal grand jury, complex fraud cases such as Enron are difficult to unravel and rarely can be charged within a year.

Id. Section 1658(b) also gives investors more time to resolve the dispute "without litigation." *Id.*

Moreover, the context and structure of the statute eliminates any parade of horribles that defendants can dream up. *See TRW Inc. v. Andrews*, 534 U.S. 19, 29-34 (2001) (examining the text and structure of a statute of limitations to interpret it). In particular, Section 1658(b) also states that no private right of action may be brought "5 years after such violation." 28 U.S.C § 1658(b).

While the two-year limitation period only begins to run when the investor discovers the facts constituting the fraud, the five-year limitation period begins to run as soon as the defendant commits the violation (i.e., breaks the law). Thus, the structure of the statute gives investors an incentive to investigate as soon as possible,

because it eliminates the hypothetically suspicious investor who refuses to investigate whether fraud has been committed.

Enron provides a good example. On November 8, 2001, Enron announced that it had overstated earnings since 1997. ACCOUNTING REFORM AND INVESTOR PROTECTION: HEARINGS BEFORE THE SENATE COMM. ON BANKING, HOUSING, AND URBAN AFFAIRS, Volume I, 107th Cong. 1 (2002).[11] On that date, no plaintiff could bring a claim under Rule 10b-5 based on conduct that occurred prior to November 8, 1998, given the three-year repose period established by *Lampf*. As a result, investors could not bring claims against Enron based on alleged securities fraud in 1997 and 1998.[12]

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11. *See* HAROLD S. BLOOMENTHAL, SARBANES-OXLEY ACT IN PERSPECTIVE 1 (2002) (stating that Enron's earnings restatement would result in reduction to reported net income of approximately $96 million in 1997, $113 million in 1998, $250 million in 1999, and $132 million in 2000).

12. *See* S. Rep. No. 107-146 at 17 (2002):

> The current statute of limitations for most securities fraud cases is three years from the date of the fraud or one year after the fraud was discovered. This can unfairly limit recovery for defrauded investors in some cases. As Washington State Attorney General Gregoire testified at the Committee hearing, in the Enron state pension fund litigation, the current short statute of limitations has forced some states to forgo claims against Enron based on alleged securities fraud in 1997 and 1998. In Washington state alone, the short statute of limitations may cost hard-working state employees, firefighters and police officers nearly $50 million in lost Enron investments, which they will never recover.

Even if Section 1658(b) applied to Enron, no plaintiff could have brought a claim under Rule 10b-5 based on conduct that occurred prior to November 8, 1996. Investors suspicious of fraud at Enron would have every incentive to investigate and file a complaint as quickly as possible, given that the five-year period would have been cutting off their claims as every day passed.[13] While Section 1658(b) is not triggered by a "duty to investigate," its structure gives investors a strong incentive to investigate potential fraud.

Because the language and design of the statute demonstrates that Section 1658(b) has a plain meaning that is not absurd, the "sole function" for this Court is "to enforce it according to its terms." *Arlington Cent. Sch. Dist. Bd. of Ed. v. Murphy*, 548 U.S. 291, 296 (2006). As this Court held in *Central Bank*, "Policy considerations cannot override our interpretation of the text and structure of the Act, except to the extent that they may help to show that adherence to the text and structure would lead to a result 'so bizarre' that Congress could not have intended it." 511 U.S. at 188.

Courts do not have "a *carte blanche* to redraft statutes in an effort to achieve that which Congress is perceived to have failed to do." *United States v. Locke*, 471 U.S. 84, 95 (1985). "Nor is the Judiciary licensed to attempt to soften the clear import of Congress' chosen words whenever a court believes those words lead to a

13. More recently, the five-year limitation has worked to dramatically eliminate claims based on the fraudulent backdating of options. *See, e.g., In re Apple Computer Inc. Derivative Litig.*, No. 06 Civ. 4128, 2007 WL 4170566, at *1 (N.D. Cal. Nov. 19, 2007).

harsh result." *Id.* Indeed, "experience teaches that strict adherence to the procedural requirements specified by the legislature is the best guarantee of evenhanded administration of the law." *Mohasco Corp. v. Silver*, 447 U.S. 807, 826 (1980).

IV. Petitioner Has Given No Persuasive Reason to Adopt "Inquiry Notice"

Petitioner gives two main reasons for interpreting Section 1658(b) so that it is triggered by "inquiry notice" despite the fact that this phrase is not found in the statute. Petitioner first points out that the concept of "inquiry notice" is "well-established." Brief for the Petitioner at 13-14. And Petitioner is correct: every circuit court has adopted "inquiry notice." *See Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 869 (9th Cir. 2008) ("[T]he courts of appeal in our sister circuits .... have uniformly embraced inquiry notice.").

But, as this Court made clear in *Central Bank*, 511 U.S. at 188, the text of a statute controls. In *Central Bank*, this Court noted that in the context of securities law, it was paying "close attention to the statutory text," *id.* at 169, and held that "[b]ecause the text of § 10(b) does not prohibit aiding and abetting ... a private plaintiff may not maintain an aiding and abetting suit under § 10(b)." *Id.* at 191. The Court reached this conclusion despite the fact that, over the previous three decades, all eleven Courts of Appeals had recognized aiding and abetting liability. *See id.* at 192 ("In hundreds of judicial and administrative proceedings in every Circuit in the federal system, the courts and the SEC have concluded that aiders and abettors are subject to liability under § 10(b) and Rule 10b-5.") (Stevens, J., dissenting).

Petitioner's second argument is that by passing 1658(b), Congress "ratified" the lower courts' adoption of "inquiry notice." Brief for the Petitioner at 13; *see Betz*, 504 F.3d at 875 (holding that "inquiry notice" should be accepted because Congress enacted Section 1658(b) and "[b]y choosing language nearly identical to the language of § 9(e), Congress implicitly approved of that case law.").

The problem with this argument is that "ratification" of existing case law is—at most—a canon of interpretation, yet the language of Section 1658(b) is clear on its face. As this Court has recently explained:

> Canons of interpretation "are quite often useful in close cases, or when statutory language is ambiguous. But we have observed before that such 'interpretative canon[s are] not a license for the judiciary to rewrite language enacted by the legislature.'"

Corley v. United States, 129 S. Ct. 1558, 1572 (2009) (quoting *United States v. Monsanto*, 491 U.S. 600, 611 (1989)).[14] When the words of the statute are unambiguous, courts do not rely on canons of

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14. *See United States v. United Mine Workers of Am.*, 330 U.S. 258, 314 (1947) (Frankfurter, J., concurring) ("[A] canon, like other generalities about statutory construction, is not a rule of law. Whatever persuasiveness it may have in construing a particular statute derives from the subject matter and the terms of the enactment in its total environment."); Karl N. Llewellyn, *Remarks on the Theory of Appellate Decision and the Rules or Canons About How Statutes Are to Be Construed*, 3 VAND. L. REV. 395 (1950).

interpretation for the simple reason that judicial inquiry is complete. *See id.*

Indeed, the majority decision in *Central Bank* teaches that Congress does not "ratify" existing case law by passing a new statute. Prior to *Central Bank*, there was widespread agreement that the statute prohibited aiding and abetting of securities fraud. And, as Justice Stevens argued in his dissent:

> Here, however, the available evidence suggests congressional approval of aider and abettor liability in private § 10(b) actions. In its comprehensive revision of the Exchange Act in 1975, Congress left untouched the sizeable body of case law approving aiding and abetting liability in private actions under § 10(b) and Rule 10b-5.

Id. at 197; *see id.* at 197 n.8.

Indeed, both parties "*assumed* the existence of a right of action against aiders and abettors, and sought review only of the subsidiary questions . . . ." *Central Bank*, 511 U.S. at 194 (Stevens, J., dissenting) (emphasis added).

> But instead of simply addressing the questions presented by the parties, on which the law really was unsettled, the Court *sua sponte* directed the parties to address a question on which even the petitioner justifiably thought the law was settled, and reaches out to overturn a most considerable body of precedent.

Id. at 194-95.

Nonetheless, the Court explained:

> We reach the uncontroversial conclusion, accepted even by those courts recognizing a § 10(b) aiding and abetting cause of action, that the text of the 1934 Act does not itself reach those who aid and abet a § 10(b) violation. Unlike those courts, however, we think that conclusion resolves the case. It is inconsistent with settled methodology in § 10(b) cases to extend liability beyond the scope of conduct prohibited by the statutory text.

Id. at 177. The fact that "the statute itself resolves the case" is, not surprisingly, consistent with this Court's jurisprudence outside the context of securities law. *See, e.g., Lexecon*, 523 U.S. 26 (overturning thirty years of uniform case law in the lower courts because of the straightforward language of a statute).

Section 1658(b) does not mention any type of "inquiry notice." The statute does not instruct courts to require a real, or hypothetical, investigation. The statute is not triggered by "storm warnings" which may, or may not, involve the "possibility" or "probability" of fraud. Figuring out the proper definition of "inquiry notice" is a run down a rabbit trail, because only two things start the section 1658(b) statute of limitations: (1) the moment the defendant commits the violation, and (2) the moment the plaintiff discovers the facts that constitute the violation, and can therefore start an action.

V. Inquiry Notice Places Extraordinary Burdens on the "Ordinary" Investor

Judicial decisions post-*Lampf* prove that courts are paying little, if any, attention to the statute. Courts hold that the limitations period begins to run not only when a plaintiff has actual knowledge of fraud, but additionally, when a "reasonable investor of ordinary intelligence would have discovered the existence of the fraud." *Dodds v. Cigna Sec., Inc.* 12 F.3d 346, 350 (2d Cir. 1993). "[M]ost circuits 'generally apply an inquiry notice standard coupled with some form of reasonable diligence requirement.'" *Berry*, 175 F.3d at 704 (quoting *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1199-1200 (10th Cir. 1998)).

To determine when this reasonable investor should have discovered fraud, courts have adopted a two-part objective test. First, courts decide when an "average" investor should have sufficient information (so-called "storm warnings") of "possible" or "probable" wrongdoing. Second, when a court finds that an average investor should have been on notice, he is obligated to investigate the potential fraud, and must discover the fraud if an average investor would have done so. For numerous reasons, "inquiry notice" imposes an extraordinary burden on ordinary investors.

A. An "Ordinary" Investor Cannot Meaningfully Determine if He Is on Sufficient Inquiry Notice to Trigger a Duty to Investigate Securities Fraud

The reasonable investor must be diligent, and a diligent reasonable investor has a duty to investigate if he has "sufficient information of possible wrongdoing to place [him] on 'inquiry notice' or to excite 'storm warnings' of culpable activity." *In re Merck*, 543 F.3d at 161 (citation omitted). However, for any investor, let alone the "average" investor, determining with any sort of precision when he is on inquiry notice is elusive. Sophisticated investors, courts, and commentators arrive at starkly different conclusions on the existence of storm warnings and when the duty to investigate accrues. The "ordinary" investor, such as a retiree or any number of individuals who do not make a living out of investing, cannot be held to this exacting standard.[15]

The "fraud on the market theory" demonstrates why this is so. The theory provides that a defendant's fraud will be reflected in the price of a security and that any plaintiff will have relied on that fraud when purchasing the security. The theory is premised on the existence of an informationally efficient market; that is, one in which any information that is publicly disclosed

15. The securities laws afford protection to all investors, sophisticated and unsophisticated. *Piper v. Chris-Craft Industs.*, 430 U.S. 1, 25-31 (1977); *Morey v. Bravo Productions, Inc.*, Civ. No. 85-10091, 1987 WL 28526, at *9 (S.D.N.Y. Dec. 2, 1987) ("the securities laws are designed to protect the unsophisticated investor, rather than the experienced businessman.").

and widely disseminated is incorporated into a security's trading price. *See Basic v. Levinson*, 485 U.S. 224, 247 (1988).

Information about the stock is incorporated into its share price through the workings of securities analysts, market makers, professional investment advisors, and other market professionals who read and evaluate all publicly available information about a company. In contrast to ordinary "reasonable investors," these career investors are paid millions of dollars a year to monitor and digest information concerning a company and its products. This includes, among other things, asking corporate insiders specific questions during company conference calls, which are often on behalf of "ordinary" reasonable investors, who are typically not permitted to ask questions. Market professionals usually issue reports that keep ordinary investors apprised of any material developments discovered as a result of their diligent investigations. And by their trading patterns, these market professionals will cause the company's stock price at any given time to reflect the totality of all publicly known information.

Yet, in the case *sub judice*, Merck's share price did not give any indication that possible securities fraud was afoot until about one week before the commencement of this lawsuit, November 6, 2003.[16] The facts before this

16. In late October 2003, two critical articles appeared about the link between Vioxx and increased risks of heart attacks. The October 22, 2003 Reuters article further reported that Merck would cut 4,400 jobs and that it posted flat earnings. On this day, Merck's share price dropped 6.5%. Also, during this time, Merck's stock fell below the S&P 500 index.

Court show that there were no indicia whatsoever that Merck did not have a good faith belief, or a reasonable basis, for the validity of its "naproxen hypothesis." [17] Virtually all independent commentators (including scientific journals and sophisticated market professionals, such as securities analysts) confirmed that Merck's naproxen hypothesis was plausible, and many even agreed with Merck that the naproxen hypothesis was the best explanation for the Vioxx Gastrointestinal Outcomes Research ("VIGOR") results.

In his dissent in *In re Merck*, Judge Roth argued that the September 21, 2001 Division of Drug Marketing, Advertising, and Communications Letter ("DDMAC Letter")[18] should have put an "ordinary" investor on notice of fraud. 543 F.3d at 173 (Roth, J., dissenting). Yet, the DDMAC Letter did not provide investors with notice of any facts suggesting that Defendants did not hold their stated opinions concerning the naproxen hypothesis in earnest or that the hypothesis lacked a reasonable basis in fact. Instead, the DDMAC Letter scolded Merck for being overly zealous in promoting Vioxx to physicians. Market analysts confirmed that the issues raised by the DDMAC Letter were already known to the market. Indeed, every analyst report issued after the DDMAC Letter either

17. The naproxen hypothesis is the theory that Vioxx's elevated incidence of cardiovascular events ("CVs") compared to naproxen was due not to Vioxx itself, but to naproxen's ability to block platelet aggregation and lower the risk of CVs.

18. The DDMAC Letter charged Merck with engaging in a promotional campaign that minimized the potentially serious CVs that were observed in previous studies and therefore minimized the safety profile of Vioxx.

maintained or raised its rating for Merck's stock and continued to project billion dollar increases in future sales of Vioxx. Consistent with this response, a number of analysts explicitly dismissed the DDMAC Letter as "routine" and a "non-event."

In sum, following a brief drop after the publication of the DDMAC Letter, in response to what one analyst characterized as market "noise," the price of Merck's stock promptly recovered after leading securities analysts and the market had time to digest the DDMAC Letter and determine that it contained no new material information. On September 27, 2001 (four trading days after the DDMAC Letter was posted on the FDA's website), Merck's stock price closed higher (at $66.21) than its closing price (of $65.70) on September 21, 2001 (the date the DDMAC Letter was posted). It is unreasonable to expect an "ordinary" investor somehow to be better at noticing fraud than the informationally efficient market, yet that is precisely the conclusion courts draw when attempting to analyze inquiry notice.

The facts before this Court, as well as *In re Merck's* disputed path through the federal courts, highlight the burdens of imposing inquiry notice on the "average" investor. Minds far more astute than the ordinary investor have weighed in, and their disagreement is substantial. Third Circuit Judges Sloviter and Barry found that there were not sufficient storm warnings, while dissenting Judge Roth, as well as district court Judge Chesler, found the opposite. Additionally, Vioxx's troubled history is rife with disagreement among Merck employees, professional investors, market watchers, industry insiders, and others over the risks posed by

the drug and whether Merck was honestly disclosing said risks. The Third Circuit's opinion highlighted numerous episodes that casted doubt on the safety of Vioxx, from internal e-mails in 1996, through the withdrawal of the drug from the market in September 2004. Seemingly, every time something negative about Vioxx was disclosed, Merck and numerous scientific and investment experts countered with contrary, largely positive findings. A fine balance was maintained throughout, resulting in total obfuscation for the ordinary investor.

Months after the withdrawal of the drug from the market, a critical *Wall Street Journal* article published on November 1, 2004 prompted one securities analyst to remark, "'new information indicates to us that the situation might not be as innocent as we thought . . . . We recommend that investors sell Merck shares.'" *Id.* at 159. On November 6, 2003, plaintiffs brought the first complaint. Presumably, at least one professional investor thought the threats surrounding Vioxx were still "innocent" up to about one year after the plaintiffs brought this suit. This contentious history demonstrates the profound level of disagreement over Vioxx and Merck's actions. If federal judges and expert investors could not reach any agreement over the possibility of fraud before and even after the filing of this suit, then the ordinary investor stands little chance. Yet, courts uniformly hold that an "ordinary" investor can and must decide precisely when to start an investigation.

B. Expecting an "Ordinary" Investor to Conduct a Meaningful Investigation into the Existence of Securities Fraud Imposes Extraordinary Burdens

The inquiry notice standard contains two distinct parts: a notice requirement, plus a duty to investigate once the investor is on notice. The investigation component penalizes the ordinary investor. First, inquiry notice creates two types of plaintiffs—those who investigate and those who do not. Of course, the latter will not discover facts sufficient to bring a viable § 10(b) complaint. However, if a court determines that this investor should have investigated, then actual knowledge of fraud is imputed to him. If two years then pass, and he fails to change his mind, conduct an investigation, find fraud, and file suit, then his claim is time barred. But even the former, the diligently investigating plaintiff, faces extreme burdens in both discovering and preserving his claim.[19]

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19. In certain contexts, an inquiry notice standard to determine the running of a statute of limitations is workable. For example, if a reasonable employee should have known that he was terminated for unlawful reasons, that employee's time to file suit would start to run. That employee would have a limited set of facts to analyze and could likely conduct a meaningful investigation into the facts behind his termination before deciding whether to bring a lawsuit. *See Dixon v. Gonzales*, 481 F.3d 324, 332 (6th Cir. 2007). Compare this context to the ordinary investor attempting to determine whether he is on notice of securities fraud and then trying to investigate the existence of fraud, while he is confronted with numerous market signals that are often in conflict and are often misunderstood by professional investors.

The limitations period starts running "from the time at which plaintiff should have discovered the general fraudulent scheme." *In re Merck*, 543 F.3d at 163 (citation omitted). Courts in several circuits have held that a claim accrues when an investor finds "facts underlying the alleged fraud." *Sterlin*, 154 F.3d at 1200. *Accord Shah v. Meeker*, 435 F.3d 244, 249 (2d Cir. 2006); *Betz*, 519 F.3d at 876; *Marks v. CDW Computer Centers, Inc.*, 122 F.3d 363, 367 (7th Cir. 1997).

However, as it is difficult to determine the possibility of fraud, it is likewise difficult to investigate and to discover the existence of fraud. In his dissent in *Lampf*, Justice Kennedy commented on the "significant" practical and legal obstacles to bringing a private § 10(b) suit. 501 U.S. at 376-77 (Kennedy, J., dissenting). These obstacles are compounded because "'[c]oncealment is inherent in most securities fraud cases.'" *Id.* at 377 (quoting American Bar Association, *Report of the Task Force on Statute of Limitations for Implied Actions*, 41 BUS. LAW. 645, 654 (1985)). Even sophisticated investors may not be able to discover fraud until long after its perpetration. *Id.* (citing *Ernst*, 425 U.S. at 189).[20]

Despite the prevalence of concealment, plaintiffs are not allowed to invoke equitable tolling to prolong the

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20. *See* Dean Foust, *Don't Shorten the Deadline on Investors' Lawsuits*, BUS. WEEK, Jan. 13, 1992, at 36 ("The time is needed because securities-fraud cases are often maddeningly complex. It takes time to discover that fraud occurred, let alone develop a case. Even the [S.E.C.], with its subpoena powers, needed more than three years . . . until it began proceedings against Drexel and E.F. Hutton.").

limitations period in § 10(b) cases. The majority in *Lampf* was clear: "The 1-year period, by its terms, begins after discovery of the facts constituting the violation, making tolling unnecessary." 501 U.S. at 363. *Accord Whirlpool Fin. Corp. v. GN Holdings, Inc.*, 67 F.3d 605, 610 n.3 (7th Cir. 1995) (citing *Tregenza*, 67 F.3d at 721). *Lampf* based its denial of equitable tolling remedies on the Court's envisioning an actual discovery regime, wherein tolling would be unnecessary. *See Ball v. Abbott Adver., Inc.*, 864 F.2d 419, 421(6th Cir. 1988) (noting that "actual knowledge destroys any possible basis for applying the 'equitable tolling' doctrine"). However, defendant's concealment would prevent an investor from discovering fraud that he should have discovered. Equitable tolling is thus necessary to preserve plaintiff's claim under inquiry notice. In short, it is difficult to reconcile the following: a court-created obligation for an ordinary investor to discover fraud through investigation, "inherent concealment" in most securities fraud cases, and the lack of equitable tolling remedies. It signals to defendants that if they can conceal securities fraud for a mere two years, then they are immune from all private actions.

Compounding plaintiffs' burdens is that courts begin the limitations period before plaintiffs have actual or even constructive knowledge of the "facts constituting the violation." *See supra* Section II.B ("Facts Constituting the Violation" Requires a Plaintiff to Be Able To State a Claim").[21] Courts have introduced more

21. In his dissent in *Betz*, Chief Justice Kozinski criticized a Ninth Circuit decision for breaking from the rulings of ten

(Cont'd)

vagueness into the inquiry notice standard. They look to determine when an "ordinary" investor should have discovered facts somewhat less than sufficient to bring a claim. This imposes extreme burdens on courts, which have to make this determination, as well as on plaintiffs and defendants. This standard encourages premature securities litigation, as investors rush to bring suits, even though they lack sufficient facts, for fear of being time barred. Companies then have to defend against numerous speculative claims.

But the party who suffers most from inquiry notice is the investor who incorrectly decides not to investigate. For this plaintiff, the limitations period begins to run immediately. The knowledge they would have presumably discovered had they investigated is simply "imputed" to them. *See Benak v. Alliance Capital Mgmt.*, 435 F.3d 396, 401 (3d Cir. 2006) ("Once on inquiry notice, plaintiffs have a duty to exercise reasonable diligence to uncover the basis for their claims, and are held to have constructive notice of all facts that could have been learned through diligent investigation during the limitations period.") (citation omitted); *LC Capital Partners v. Frontier Ins. Group*, 318 F.3d 148, 154 (2d Cir. 2003) ("If the investor makes no inquiry once the duty arises, knowledge will be imputed as of the date

(Cont'd)

other circuits and holding that an investor must be able to bring a viable claim before that claim accrues: "The [Ninth Circuit majority] panel cites no authority supporting its curious notion that an investor isn't on inquiry notice until he has concrete proof of every element of his claim, including scienter. There is no such authority; ten circuits disagree." 519 F.3d at 867-68 (Kozinski, C.J., dissenting).

the duty arose."). Section V.A documented how difficult it is for an "ordinary" investor to decide correctly whether an investigation is necessary. But the consequences of making the wrong decision can be devastating—the loss of all redress against potentially substantial fraud. Investors are therefore encouraged to investigate even the smallest possible fraud. This is wasteful. With such a short and strict limitations period, ordinary investors cannot afford to wait to see how the facts develop and to ensure they have a bona fide claim before filing a complaint in court.

It is unreasonable to expect an "ordinary" investor to determine accurately when a duty to investigate securities fraud arises, and then to expect the ordinary investor to conduct a meaningful investigation into the existence of that fraud. "Inquiry notice" imposes burdens on ordinary investors that are not required by the statute. This Court should correct that error.

CONCLUSION

Section 1658(b) should be read according to its plain meaning: the two-year limitation period should start when the investor discovers (i.e., has actual knowledge of) the facts constituting the violation (i.e., facts that state a claim). Whatever policy arguments could be made for, or against, "inquiry notice" should be left to Congress. This Court should enforce the statute as it is written.

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MERCK & CO., INC., ET AL., PETITIONERS

v.

RICHARD REYNOLDS, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

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BRIEF FOR CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

The Chamber of Commerce of the United States of America respectfully submits this brief as amicus curiae in support of petitioners.[1]

INTEREST OF AMICUS CURIAE

The Chamber of Commerce of the United States of America is the world's largest business federation. The Chamber represents an underlying membership of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files amicus curiae briefs in cases that raise issues of concern to the Nation's business community.

The Chamber and its members recognize the importance of the federal securities laws to deter and

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[1] Pursuant to Rule 37.3(a), blanket letters from the parties consenting to the filing of this brief have been filed with the Clerk of the Court. No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of the brief. No person other than amicus curiae, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

remedy wrongdoing to investors. Amicus and its members are concerned, however, that the expansive standard for the statute of limitations in private securities fraud actions articulated by the court of appeals will lead to further proliferation of securities fraud actions that will undermine the goals of our federal securities laws and threaten the health and stability of our capital markets. The court of appeals' holding in this case potentially eliminates an otherwise valid statute of limitations defense in many securities fraud actions.

Securities fraud actions are subject to a two-year statute of limitations "after the discovery of the facts constituting the violation." 28 U.S.C. § 1658(b)(1). But under the ruling below, that statute of limitations does not commence—even when a plaintiff possesses concrete evidence of the possibility of fraud—until the plaintiff has, in effect, all the facts necessary to file a viable complaint. Not only is there no basis for that conclusion in the text or purpose of the statute, that expansive standard undermines this Court's longstanding rationale behind the discovery rule in statutes of limitations by allowing plaintiffs to ignore, rather than diligently investigate, their potential claims.

Accordingly, amicus and its members have a strong interest in this Court's reversal of the decision below to ensure proper application of the two-year statute of limitations in securities fraud cases across the country.

SUMMARY OF ARGUMENT

A. 1. The statute of limitations in 28 U.S.C. § 1658(b)(1), which bars securities fraud claims brought more than two years after the "discovery of the facts constituting the violation," begins to run when the plaintiff knows or should know of the possibility of securities fraud. The court of appeals held to the contrary, concluding that the limitation period does not begin to run until the plaintiff knows or should know information specifically relating to each element of the claim, including scienter. That holding cannot be squared with the text of the statute.

When, as here, a statute of limitations incorporates a discovery rule, a plaintiff need not have information specifically relating to each element of his cause of action to trigger the running of the limitations clock. Rather, once a plaintiff has information sufficient to alert him to the possibility of a claim, the plaintiff is obligated to investigate whether the defendant's conduct is actionable, and the limitation period is the time to do so. That was the longstanding construction of discovery rules when Congress enacted Section 1658(b), and Congress should be presumed to have incorporated that settled meaning.

Congress's use of the phrase "facts constituting the violation" in Section 1658(b)(1) further supports that a plaintiff need not possess "facts sufficient to state a cause of action" before the two-year period

begins to run. As this Court has made clear, a plaintiff must prove more than "a violation" of Section 10(b) to prevail on a securities fraud claim. At a minimum, the phrase "facts constituting the violation" is best understood as referring to the core facts concerning the defendant's conduct, and not the defendant's state of mind.

2. The structure of Section 1658(b)—with its two separate, alternative time bars—confirms that the court of appeals' construction is misplaced. Under that lax interpretation of the two-year limitation period, the five-year period of repose would almost always be the only effective time limitation. That interpretation, which would effectively write the two-year limitation period off the books, should be rejected.

3. Under the court of appeals' reading of Section 1658(b)(1), no logical purpose would have been served by its enactment. When Congress codified the limitation period announced by this Court in *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991), the sole change it made was to extend the limitation period from one year to two. If the court below were correct, that extension would make no sense. In the court of appeals' view, the limitation period does not even begin to run until the plaintiff possesses all the facts necessary to file a viable complaint under the Private Securities Litigation Reform Act of 1995 (PSLRA), Pub. L. No. 104-67, 109 Stat. 737. But that would mean that Congress provided potential plaintiffs an extra

year—twice the amount of time that they previously had—solely for the purpose of *drafting* an already thoroughly investigated complaint. The only reading of the extension that makes sense is that Congress sought to provide plaintiffs additional time to conduct an investigation into possible securities fraud so that they could uncover enough facts to meet the heightened pleading standards of the PSLRA, not to give them an additional year once they already had enough information to file a viable complaint.

4. The ruling below undermines the policies behind statutes of limitations, which encourage prompt investigation and initiation of claims to preserve a defendant's ability to present a defense and to provide clarity as to when legal action is foreclosed. Contrary to those fundamental principles, the decision below encourages potential plaintiffs who are aware of the possibility of fraud to sit back and watch the price of their stock before deciding whether to bring suit, rather than launch a diligent inquiry.

B. If the Court nevertheless concludes that Section 1658(b)(1) allows a plaintiff some period of time to conduct an investigation before the two-year period begins to run, the Court should also hold that the statute of limitations continues to run unless the plaintiff himself actually conducts a reasonable, diligent investigation. In some circuits, the clock does not start ticking until after the period of time it would have taken a hypothetical reasonable plaintiff to conduct an investigation and discover the alleged fraud, regardless of whether the plaintiff undertakes

a reasonably diligent inquiry. But this Court has long recognized that the discovery rule is available only to plaintiffs who exercise reasonable diligence in discovering the fraud. *See, e.g.*, *Bailey v. Glover*, 88 U.S. (21 Wall.) 342, 348 (1875).

Moreover, such an "inquiry notice plus hypothetical diligence" rule would prove unworkable in practice. It would require the court to conceive, in a vacuum, what a hypothetical diligent investigation would have entailed and would have uncovered, without regard to what the plaintiff actually did.

C. Securities class actions, by their nature, present "a danger of vexatiousness different in degree and in kind from that which accompanies litigation in general." *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 739 (1975). Congress recognized that when it enacted checks on private securities litigation. It is implausible to believe that in enacting Section 1658(b), Congress intended to permit stale securities actions in which potential plaintiffs have undertaken no investigation after they were put on notice of the possibility of fraud. Yet under the court of appeals' rule, the statute of limitations under Section 1658(b)(1) becomes an open-ended inquiry, and the ability to cut off stale claims through that limitation provision is greatly diminished. Those stale claims become more difficult to defeat, not due to any merit but because memories fade and older records must be recovered. The impact of such abusive securities class actions on the Nation's economy is already severe, and the court of appeals' rule would only exacerbate it.

Securities class actions that survive a motion to dismiss and enter the discovery phase exert enormous pressure on defendants to settle. The huge costs associated with discovery in these cases combined with the potential for devastating damages awards dramatically boost settlement values of even the least meritorious claims. It is critical, therefore, that the standard for the running of the limitation period be sufficiently rigorous to cut off stale claims at an early stage. The court of appeals' lax rule would permit more securities class actions to move beyond the motion-to-dismiss stage and would encourage the filing of additional class actions. That would impose undue burdens on the Nation's economy.

ARGUMENT

THE COURT OF APPEALS' READING OF 28 U.S.C. § 1658(b)(1) CANNOT BE RECONCILED WITH ITS TEXT, STRUCTURE, PURPOSE, AND HISTORY AND ENCOURAGES PLAINTIFFS TO SIT ON THEIR POTENTIAL SECURITIES FRAUD CLAIMS RATHER THAN DILIGENTLY INVESTIGATE ANY POSSIBLE FRAUD

Section 1658(b) of Title 28 bars a private suit brought pursuant to Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5, of the Securities and Exchange Commission (SEC) if the suit is filed more than "2 years after the discovery of the facts constituting the violation" or "5 years after such violation," whichever is earlier. 28 U.S.C. § 1658(b).

The text and purpose of that limitation provision compel the conclusion that a suit filed by a private plaintiff is time-barred if the plaintiff has known or should have known of the possibility of securities fraud by the defendant—*i.e.*, has been on inquiry notice—for more than two years. Any other reading would encourage plaintiffs to sit on their potential claims rather than diligently investigate any possible fraud.

The court below nonetheless held that a plaintiff who suspects (or should suspect) that the defendant made a material misrepresentation is not on notice of the possibility of fraud until that plaintiff has information specifically relating to whether the defendant "h[e]ld those opinions or beliefs in earnest." Pet. App. 33a. Under that construction of Section 1658(b)(1), the two-year statute of limitations does not commence until a plaintiff has knowledge of all the elements of his claim—including evidence of scienter—and can adequately plead a securities fraud cause of action. Pet. App. 29a-30a. That conclusion should be rejected.

A. Section 1658(b)(1) Requires A Private Plaintiff To Bring A Securities Fraud Action Within Two Years After He First Suspects, Or Has Reason To Suspect, The Possibility Of Fraud On The Part Of The Defendant

In enacting Section 1658(b), Congress codified the statute of limitations for private securities actions

that this Court announced in *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991). At the time of *Lampf*, no provision expressly established a limitation period for a private right of action under Section 10(b) or Rule 10b-5, because neither Congress nor the SEC had contemplated the existence of such an action. Looking to the statute of limitations found in Section 9(e) of the Securities Exchange Act of 1934, 15 U.S.C. § 78i(e), this Court held that actions pursuant to Section 10(b) and Rule 10b-5 must be commenced "within one year after the discovery of the facts constituting the violation and within three years after such violation." *Lampf*, 501 U.S. at 364; *see id.* at 364 n.9. In 2002, Congress adopted that judicial construct with only one modification: it extended the statute of limitations to "2 years after the discovery of the facts constituting the violation," and lengthened the period of repose to "5 years after such violation." 28 U.S.C. § 1658(b).

1. The text of Section 1658(b)(1) requires a plaintiff to bring his claim within two years after he is on notice of the possibility of fraud

a. Section 1658(b) requires a private cause of action for securities fraud to commence two years after "discovery of the facts constituting the violation" of the securities laws. 28 U.S.C. § 1658(b)(1). That statutory text—"*discovery* of the facts constituting the violation"—expressly incorporates a discovery rule into the statute of limitations. As explained below, that means that the clock begins to run when the

plaintiff first suspects (or has reason to suspect) the possibility of fraud on the part of the defendant. At that point, a prospective plaintiff is obligated to investigate his potential claims, and the limitation period continues to run while he does so. A plaintiff need not possess information specifically relating to each element of his cause of action for the limitation period to begin.

When applying a discovery rule to limitation periods, this Court has long made clear that a plaintiff need not have information specifically relating to each element of his cause of action to start the running of the clock. *See Rotella v. Wood*, 528 U.S. 549, 555 (2000). For example, in *United States v. Kubrick*, 444 U.S. 111 (1979), the Court held that the limitation period in the Federal Tort Claims Act begins to run as soon as the plaintiff knows the "critical facts that he has been hurt and who has inflicted the injury." *Id.* at 122. At that point, the claim has "accrue[d]," because a plaintiff armed with those facts is on notice that he must promptly investigate whether the defendant's conduct in causing the injury was tortious and therefore actionable. As the Court explained, the limitation trigger does not await the completion of the plaintiff's investigation: that "would undermine the purpose of the limitations statute, which is to require the reasonably diligent presentation of * * * claims." *Id.* at 123.

Likewise, in *Rotella*, the Court held that the statute of limitations for private civil claims under the Racketeer Influenced and Corrupt Organizations Act (RICO) begins running before the plaintiff possesses knowledge of a key element of a civil RICO cause of action—namely, a pattern of racketeering activity. *Rotella*, 528 U.S. at 554. The limitation period is triggered, at the latest, when the plaintiff knows or should know of his injury, even if he has no facts supporting the requisite pattern of activity. *Id.* at 554 & n.2. As the Court explained, despite the potential complexities of some RICO patterns and the enormous difficulty a plaintiff may face in uncovering them, once the plaintiff knows or should know of an injury, he is on inquiry notice and must "investigate the cause of his injuries" while the clock for him to bring suit continues ticking. *Id.* at 557. Otherwise, the limitation period would effectively be open ended, thereby "prov[ing] a godsend to stale claims, and doom[ing] any hope of certainty in identifying potential liability." *Id.* at 559.

Moreover, when Congress enacted Section 9(e) of the Securities Exchange Act of 1934, 15 U.S.C. § 78i(e), it had been well established that the limitation clock starts to tick as soon as a plaintiff is on inquiry notice of the possibility of a claim and continues to run while the plaintiff is investigating the potential fraud. *See United States v. Diamond Coal & Coke Co.*, 255 U.S. 323, 335 (1921) (discussing whether particular facts known to the plaintiff "constituted such indications of fraud as to give notice

to the [plaintiff], or at least to put it upon inquiry"); *Wood v. Carpenter*, 101 U.S. 135, 141 (1879) ("Whatever is notice enough to excite attention and put the party on his guard and call for inquiry is notice of every thing to which such inquiry might have led." (quoting *Kennedy v. Greene*, 3 Myl. & K. 722, 40 Eng. Rep. 266, 275 (Ch. 1834) (opinion of Lord Brougham))); *see also* John P. Dawson, *Fraudulent Concealment and Statutes of Limitation*, 31 Mich. L. Rev. 875, 886 (1933) (once there is evidence of a misrepresentation, "a 'duty' to investigate appears and the sanction of this 'duty' is the commencement of the statutory period"). Both the holding in *Lampf* and the text of Section 1658(b) are based on Section 9(e), which has identical "discovery of the facts constituting the violation" language. *See* 15 U.S.C. § 78i(e).

Accordingly, given the Court's longstanding construction of discovery rules, it should be presumed that Congress intended Section 1658(b)'s discovery rule to be construed the same way. *See, e.g.*, *Commissioner v. Keystone Consol. Indus., Inc.*, 508 U.S. 152, 159 (1993). The rationale articulated in cases such as *Kubrick* and *Rotella* is equally applicable here: a plaintiff who is on notice of the possibility of securities fraud should be encouraged to promptly investigate it, and a lax limitation period would "only have the effect of postponing whatever

public benefit" private securities actions might realize. *Rotella*, 528 U.S. at 558.[2]

b. If Congress had intended Section 1658(b) to have the meaning attributed to it by the court below, it could have triggered the limitation period on the "discovery of the facts sufficient to state a cause of action" or on the "discovery of the elements of a claim for securities fraud." But Congress did not do so, and this Court should not read that language into the statute. That those words should not be read into the statute is particularly so in the context of securities claims. As this Court has repeatedly recognized, to prevail in a private securities fraud action, a plaintiff must prove more than just a "violation" of Section 10(b). *See Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341 (2005) (listing elements of claim for securities fraud). Thus, in the context of a securities fraud claim, the phrase "facts constituting the

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[2] When Congress enacted Section 1658(b), it was also well established that "discovery" encompassed both actual and constructive discovery. *See Kirby v. Lake Shore & Mich. S. R.R. Co.*, 120 U.S. 130, 134-135, 138 (1887) (construing statute that runs from "the discovery by the aggrieved party of the facts constituting the fraud" as commencing when the "fraud was, or should with due diligence have been, discovered"); *see also Berry v. Valence Tech., Inc.*, 175 F.3d 699, 703-704 (9th Cir. 1999) (collecting cases). Thus, there is universal agreement among the circuits (in which the government concurs) that "discovery of the facts constituting the violation" encompasses both actual and constructive discovery. Brief for the United States as Amicus Curiae at 7, *Trainer Wortham & Co. v. Betz*, No. 07-1489 (U.S. Apr. 22, 2009) (quoting *Lampf*, 501 U.S. at 363).

violation" is naturally read as not encompassing all of the facts necessary to adequately plead a cause of action.

At the very least, the plain meaning of the phrase "facts constituting the violation" does not encompass facts relating specifically to scienter. Rather, that phrase is better understood as reflecting the core facts concerning the defendant's conduct, and not the defendant's state of mind. That understanding is one that is practical and logical, as it would commence the statute of limitations upon facts that are outwardly observable and would not turn on the possession of facts specifically relating to the defendant's "opinions or beliefs" and whether they were held in "earnest." Pet. App. 33a.

Indeed, in the PSLRA, Congress distinguished between those two concepts in the context of securities fraud claims. *Compare* 15 U.S.C. § 78u-4(b)(1) (requiring a plaintiff to "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading"), *with* 15 U.S.C. § 78u-4(b)(2) (requiring a plaintiff to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind"). In summarizing that distinction, this Court stated that "[t]he PSLRA, requires plaintiffs to state with particularity both the *facts constituting the alleged violation*, and the facts evidencing scienter." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) (emphasis added). The Court's use of the phrase "facts constituting the alleged violation"

(in contradistinction to facts evidencing scienter) demonstrates that, in ordinary English, the former phrase does not necessarily encompass facts relating to scienter.

c. For the foregoing reasons, the government is incorrect in suggesting that "[t]he phrase 'facts constituting the violation' is naturally understood to refer to facts that, if pleaded in a securities-fraud complaint, would be sufficient to survive a motion to dismiss." Brief for the United States as Amicus Curiae at 9, *Trainer Wortham & Co. v. Betz*, No. 07-1489 (U.S. Apr. 22, 2009). According to the government, that standard for the commencement of the limitation period is highlighted by the heightened pleading requirements of the PSLRA and Rule 9(b) of the Federal Rules of Civil Procedure. *Id.* at 9 n.2. But this Court has held that a heightened pleading standard, such as the one imposed by the PSLRA, is irrelevant to the question when the limitation period starts. *See Rotella*, 528 U.S. at 560. Indeed, Congress imposed the PSLRA standard—like other heightened pleading standards—to deter "abusive litigation," *Tellabs*, 551 U.S. at 313. It is thus quite doubtful that Congress intended that pleading standard to obviate any requirement that a plaintiff diligently investigate his potential private securities claims.

In any event, even if the interplay between Section 1658(b) and the PSLRA were to result in some claims being dismissed, that result would not be contrary to the intent of Congress. Because the five-year statute of repose bars a private securities

fraud action even if the plaintiff is blamelessly ignorant of the fraud, *see* 28 U.S.C. § 1658(b)(2), Congress clearly contemplated that not every potential securities fraud would be actionable.

2. *The structure of Section 1658(b) confirms that notice of the possibility of fraud triggers the running of the two-year statute of limitations*

The structure of Section 1658(b) confirms that a plaintiff need not possess information relating to each element of his cause of action to trigger the running of the two-year statute of limitations. Under Section 1658(b), a claim for securities fraud can be time-barred in one of two ways: if the plaintiff does not file within two years of "discovery of the facts constituting the violation" or if he does not file within 5 years "after such violation," whichever is earlier. 28 U.S.C. § 1658(b). The five-year period of repose thus serves as the outer limit for a securities fraud claim, even if a potential plaintiff is completely unaware (and has no reason to be aware) that he has a securities fraud claim.

Under the approach adopted by the court below, however, that alternative five-year limit would nearly always be the only effective time limitation on a securities fraud claim. The facts of this case illustrate why that is so. Respondents base their claims on statements made in March and April of 2000. Pet.

App. 7a-8a. Even though the Federal Drug Administration warned in a September 2001 letter that those statements were "false, lacking in fair balance, or otherwise misleading," *id.* at 11a (citation omitted), the court below nevertheless held that respondents were not on inquiry notice until October 2003, *see id.* at 18a, 47a. But by that point, less than two years remained in the five-year repose period. Thus, under the court of appeals' approach, that five-year limitation would be the only possible time bar to respondents' suit.

If that is the effect in this relatively straightforward case—where a federal agency uncovered the allegedly fraudulent or misleading nature of the statements—the court of appeals' approach would "effectively write[ ] the [two-year] statute of limitations off the books" for the vast majority of cases. *See Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 878 (9th Cir. 2008) (Kozinski, C.J., dissenting from denial of rehearing *en banc*). That could not have been what Congress contemplated when it provided for two separate, alternative time bars. *See, e.g.*, *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant * * * ." (quoting 2A N. Singer, Statutes and Statutory Construction § 46.06, pp. 181-186 (rev. 6th ed. 2000) (footnotes omitted))).

3. There would have been no logical purpose for Congress to extend the statute of limitations to two years if plaintiffs were not expected to investigate possible fraud claims during that period

a. Before the enactment of Section 1658(b), securities fraud actions pursuant to Section 10(b) and Rule 10b-5 had to be brought within the time limitation judicially established by this Court in *Lampf*, namely, "within one year after the discovery of the facts constituting the violation and within three years after such violation." *Lampf*, 501 U.S. at 364. The sole change effected by Congress's passage of Section 1658(b) was to extend the limitation and repose periods to two years and five years, respectively. 28 U.S.C. § 1658(b)(1) and (2).

If the limitation period does not begin to run until the *completion* of any investigation, the addition of that year would make no sense. Under that reading, all that would remain to be done once the limitation period begins to run would be the drafting of the complaint. But there is no reason to believe, and every reason to doubt, that Congress provided an additional year—twice the previous limitation period—solely for that purpose. Instead, the only reading of Section 1658(b)(1) that makes sense is that the limitation period begins to run as soon as a plaintiff is on inquiry notice, *i.e.*, when the plaintiff first suspects (or has reason to suspect) the possibility of fraud on the part of the defendant. The additional

year provides plaintiffs more time to investigate potential wrongdoing so as to obtain enough information to file a viable complaint under the heightened pleading requirements of the PSLRA.

b. The legislative history of Section 1658(b), which was part of the Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745, confirms that Congressional purpose and indicates that Congress contemplated that the limitation period begins to run upon notice of the possibility of fraud.

The Senate Report expressed concern that the one-year/three-year period unduly limited the ability of plaintiffs to obtain recovery, especially in cases involving complex fraud. *See* S. Rep. No. 107-146, at 8 (2002). With regard to the one-year period, the Senate Judiciary Committee reported that the period was insufficient because "the best cons are designed so that even after victims are cheated, they will not know who cheated them, or how. Especially in securities fraud cases, the complexities of how the fraud was executed often take well over a year to unravel, even after the fraud is discovered." *Id.* at 9. The Senate Report noted that "[w]ith the higher pleading standards that also govern securities fraud victims [sic], it is unfair to expect victims to be able to negotiate such obstacles in the span of 12 months (See 15 U.S.C. § 78u-4)." *Ibid.*

Additionally, the Senate Report expressed concern that, because plaintiffs had only one year to investigate the fraud once they were placed on

inquiry notice, the short period "set[] up a perverse incentive for victims to race into court, so as not to be barred by time, and immediately sue." *Id.* at 9. The Report observed that "[p]laintiffs who wish[ed] to spend more time *investigating* the matter * * * [were] punished under the [then] current law." *Ibid.* (emphasis added). Thus, the Report indicated an intent to provide plaintiffs additional time to investigate the fraud and therefore "to discourage frivolous cases." *Ibid.*

Eight members of the Senate Judiciary Committee expressly added, in accord with the statements in the main Senate Report, that the bill was "intended to be consistent with established case law in that the 'discovery' limitations period for private antifraud actions under section 10(b) of the Exchange Act begins to run when the plaintiff is on 'inquiry notice' of a fraud." *Id.* at 29. They defined "inquiry notice" as "[w]hen 'the circumstances would suggest to an investor of ordinary intelligence that she has been defrauded.'" *Ibid.* (quoting *Dodds v. Cigna Sec., Inc.*, 12 F.3d 346, 350 (2d Cir. 1993), *cert. denied*, 511 U.S. 1019 (1994)).

4. The decision below cannot be reconciled with the policies that undergird statutes of limitations

a. Statutes of limitations represent a legislative judgment that at some point the right of a defendant to be free from stale claims prevails over the right of

a plaintiff to bring his claim. *Kubrick*, 444 U.S. at 117. That judgment is founded on the principle that the passage of a large amount of time following alleged wrongdoing prejudices a defendant's ability to present a meritorious defense. Construing the limitation period in Section 1658(b)(1) as beginning to run on notice of the possibility of fraud furthers that principle: it discourages potential plaintiffs from waiting until the full fraud reveals itself and to instead "tak[e] the actions necessary to bring the fraud to light." *Brumbaugh v. Princeton Partners*, 985 F.2d 157, 162 (4th Cir. 1993).

In contrast, the court of appeals' construction of Section 1658(b)(1) fundamentally conflicts with that principle by encouraging potential plaintiffs to engage in a "wait-and-see approach" before investigating and potentially uncovering any fraud. Under that view, potential plaintiffs have every incentive to ignore the possibility of fraud because, absent evidence specifically relating to scienter, a failure to investigate will not prevent them from bringing suit much later. And in fact, by delaying, a potential plaintiff can "sit back and * * * see how the price of his stock behave[s] in the interim." *Fujisawa Pharm. Co., Ltd. v. Kapoor*, 115 F.3d 1332, 1337 (7th Cir. 1997) (Posner, C.J.). "If the stock rebound[s] from the cellar they would have investment profits, and if it stay[s] in the cellar they would have legal damages. Heads I win, tails you lose." *Tregenza v. Great Am. Commc'ns Co.*, 12 F.3d 717, 722 (7th Cir. 1993) (Posner, C.J.), *cert. denied*, 511 U.S. 1085 (1994); *see*

also Jensen v. Snellings, 841 F.2d 600, 607 (5th Cir. 1988) (inquiry notice standard is "intended to ensure fairness to defendants against claims that have been allowed to slumber") (internal quotation marks and citation omitted). That result is completely at odds with the principle underlying the two-year limitation period of Section 1658(b)(1).

But it is precisely the tactic used in this case. Even though the FDA had issued its warning letter and concerns over Vioxx had been well publicized, *see* Pet. App. 11a, 15a, 18a, the first Vioxx-related class action complaint for securities fraud was not filed until shortly after Merck's stock price dropped considerably in November 2003, *see* Pet. Br. 7. The drop in stock price then precipitated an onslaught of 16 securities fraud actions, including this one. *Ibid.* Such tactical delay on the part of plaintiffs is completely at odds with the principle behind the limitation period of Section 1658(b)(1). *See Fujisawa*, 115 F.3d at 1334 ("On this view, the potential plaintiff can complete his investigation, draft his complaint, and put the complaint in a drawer to be taken out in a year if the price of the stock has fallen."); *Royal Air Props., Inc. v. Smith*, 312 F.2d 210, 213-214 (9th Cir. 1962) ("The purpose of the Securities Exchange Act is to protect the innocent investor, not one who * * * waits to see how his investment turns out before he decides to invoke the provisions of the Act.").

b. Statutes of limitations are supposed to provide a defendant "the security of knowing when legal action against him has been foreclosed."

Brumbaugh, 985 F.2d at 162. The approach of the court below provides no such security. Rather, under such an approach, plaintiffs have "a wide choice of times at which to sue within a three-year period * * * [based on an] opportunistic use of federal securities law," and defendants thus face significant uncertainty about whether legal action will be forthcoming. *Tregenza*, 12 F.3d at 722. That is especially significant given the extraordinarily high costs imposed on defendants in securities lawsuits. *See* pp. 29-37, *infra*.

By contrast, commencing the limitation period at the moment a potential plaintiff is placed on notice of the possibility of fraud provides a clear rule for plaintiffs and defendants alike. And it is a rule that is capable of being consistently administered by federal courts, as demonstrated by the rulings of the four circuits that have adopted it. *See Franze v. Equitable Assurance*, 296 F.3d 1250, 1255 (11th Cir. 2002); *Jensen v. Snellings*, 841 F.2d 600, 608 (5th Cir. 1998); *Great Rivers Coop. of Se. Iowa v. Farmland Indus., Inc.*, 120 F.3d 893, 898-899 (8th Cir. 1997); *Caviness v. Derand Res. Corp.*, 983 F.2d 1295, 1303 (4th Cir. 1993). Because whether a plaintiff knew (or should have known) "facts constituting the violation" is an objective inquiry, a court administering such a rule can ordinarily identify the discrete event or events that first placed the plaintiff on notice.

B. At Most, A Private Plaintiff Should Be Allowed Additional Time To Investigate His Claim Only If He Actually Conducts A Reasonable, Diligent Investigation

For the reasons discussed above, the Court should hold that the limitation period in Section 1658(b)(1) begins to run when the plaintiff is on inquiry notice—*i.e.*, when the plaintiff knows or should know of the possibility of fraud. If, however, the Court concludes that Section 1658(b)(1) allows a plaintiff some additional period of time to conduct an investigation, it should allow that additional time only if the plaintiff actually conducts a reasonable, diligent investigation.

1. Several courts of appeals have held that inquiry notice does not immediately commence the running of the statute of limitations, but instead that the clock starts ticking only after the period of time it would have taken a reasonable plaintiff to conduct an investigation and discover the alleged fraud. *See, e.g.*, *New England Health Care Employees Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003), *cert. denied*, 540 U.S. 1183 (2004); *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1201 (10th Cir. 1998); *Law v. Medco Research, Inc.*, 113 F.3d 781, 786 (7th Cir. 1997). Under that approach, the investigation period is purely hypothetical, without regard to what kind of investigation, if any, the plaintiff actually undertook. Accordingly, in those circuits, the plaintiff can take advantage of whatever additional time a

hypothetical reasonable plaintiff might have needed to develop all the facts necessary to file a complaint (*plus* 2 years from that date), regardless of whether the plaintiff himself acted reasonably and conducted a diligent investigation. *See, e.g.*, *Marks v. CDW Computer Ctrs., Inc.*, 122 F.3d 363, 368 (7th Cir. 1997) (clock "does not begin to run unless and until the investor is able, with the exercise of reasonable diligence (whether or not actually exercised), to ascertain the information needed to file suit").

2. There is no basis for giving a plaintiff the benefit of the time it would take a hypothetical reasonable plaintiff to conduct an investigation if the plaintiff himself has not actually conducted a reasonable investigation. To be sure, as a matter of equity, this Court has incorporated the discovery rule into periods of limitation in cases involving fraud. *See, e.g.*, *Holmberg v. Armbrecht*, 327 U.S. 392, 397 (1946); *Bailey v. Glover*, 88 U.S. (21 Wall.) 342, 348 (1875). But, as discussed above (pp. 9-13, *supra*), Congress already expressly included that rule in the two-year limitation period in Section 1658(b)(1); those cases thus provide no support for further extending the two-year period. *See Lampf*, 363 U.S. at 350 (incorporating the discovery rule and rejecting equitable tolling of the statute of repose). At the very least, if this Court is inclined to alter its longstanding construction of the discovery rule to hold that the two-year period commences at some point after a plaintiff is on inquiry notice of the possibility of fraud, it would be fundamentally inconsistent with the

discovery rule's equitable principles to provide the benefit of any additional time to a potential plaintiff who has failed to undertake a reasonable, diligent investigation. Rather, at most, the running of the statute of limitations should be forestalled only if and while the plaintiff himself conducts a diligent inquiry.

This Court has long held that the discovery rule is available only to a plaintiff who exercises reasonable diligence in discovering his claim. In *Bailey v. Glover*, the Court announced the rule that the statute of limitations for a party injured by fraud "does not begin to run until the fraud is discovered," but only if that party "remains in ignorance of [the fraud] without any fault or want of diligence or care on his part." 88 U.S. at 348. And the Court explained in *Wood v. Carpenter* that a "party seeking to avoid the bar of the statute on account of fraud must aver and show that he used due diligence to detect it." 101 U.S. at 141; *see* 2 Calvin W. Corman, *Limitation of Actions* § 11.5.1, at 186 (1991) ("Under the federal equitable tolling doctrine, concealment of fraudulent conduct tolls the running of the statute of limitations in favor of the defrauded party until that party learns of the fraudulent conduct of the opposing party, provided the defrauded party could not have discovered it at an earlier date by the exercise of reasonable diligence."); *id.* § 11.5.6, at 198 ("Failure to discover fraud due to negligence or acquiescence precludes its assertion as the basis for tolling the applicable statute of limitations."); *cf. Klehr v. A. O. Smith Corp.*, 521 U.S. 179, 194 (1997) (concluding for

civil RICO statute of limitations that "'reasonable diligence' does matter, and a plaintiff who is not reasonably diligent may not assert 'fraudulent concealment'").

Moreover, a "fundamental principle" on which the discovery rule rests is the equitable doctrine of laches: *i.e.*, the doctrine that a plaintiff who sleeps on his rights is not entitled to pursue his claim. *Diamond Coal*, 255 U.S. at 334. Under that doctrine, "failure to make inquiry" may "take the case out of the equitable principle by which the positive bar of the statute could be avoided." *Id.* at 333. Thus, the doctrine of laches has long been "reflected in the requirement of diligence in 'discovering' the defendant's fraud." John P. Dawson, *Undiscovered Fraud & Statutes of Limitation*, 31 Mich. L. Rev. 591, 632 (1933). Failure to engage in diligence to discover the fraud results in forfeiture of the discovery rule's benefits.

Accordingly, the rule of some circuits that automatically gives a plaintiff additional time after he is on inquiry notice before the limitation period begins, regardless of the reasonableness or diligence of the plaintiff's investigatory efforts, cannot be squared with fundamental, longstanding principles animating the federal discovery rule. That background understanding, which Congress gave no sign of altering, was well settled when Congress enacted Section 1658(b) and Section 9(e) of the 1934 Act, on which Section 1658(b) is based. There is no reason to believe that Congress intended to give the

unreasonable plaintiff—*i.e.*, one who is on inquiry notice of the possibility of fraud, and yet who does not conduct a diligent inquiry—any more than two years from notice of the possibility of fraud.

3. Such an "inquiry notice plus hypothetical diligence" rule also would be unworkable. The amount of time it should take to investigate and uncover the alleged fraud is measured by the purely theoretical inquiry of what a hypothetical reasonable plaintiff would have done. In essence, courts have to conceive in a vacuum what a diligent investigation would look like and how much time it would take to complete; what the plaintiff actually did is irrelevant. That exercise would be all the more crucial, and yet all the more difficult, where the plaintiff did not actually conduct any investigation at all.

By contrast, a rule that allows the plaintiff a period to investigate only if he has acted diligently has the virtue of calling for examination of the plaintiff's actual conduct to see whether it was objectively reasonable. And, of course, if the plaintiff has not completed any investigation at all, his conduct is per se unreasonable, and the statute of limitations should begin to run as soon as he is on inquiry notice. *See LC Capital Partners, LP v. Frontier Ins. Group, Inc.*, 318 F.3d 148, 154 (2d Cir. 2003) ("If the investor makes no inquiry once the duty arises, knowledge will be imputed as of the date the duty arose.").

4. Finally, a rule that gives all plaintiffs the benefit of what a reasonable plaintiff would have done, regardless of the plaintiff's actual diligence or neglect, would unfairly reward the lax plaintiff. It would not provide incentive to potential plaintiffs to make prompt inquiry into possible wrongdoing, but rather would encourage a wait-and-see approach of sitting on the sidelines to see if someone else will uncover wrongdoing. *Cf. Brumbaugh*, 985 F.2d at 162 ("Merely bringing suit after the scheme has been laid bare through the efforts of others, in this case the IRS, will not satisfy the requirements of due diligence when there have been prior warnings that something was amiss."). Thus, if the Court were to adopt some sort of "inquiry notice plus investigation" rule, any such rule should be tempered by the requirement that the period for investigation is available only to plaintiffs who actually conduct a diligent inquiry. *See Klehr*, 521 U.S. at 194.

C. Allowing Stale Claims To Survive Will Increase Pressure On Defendants To Settle Securities Class Actions And Will Impose Undue Costs On The Nation's Economy

As both this Court and Congress have repeatedly recognized, private securities fraud litigation presents "a danger of vexatiousness different in degree and in kind from that which accompanies litigation in general." *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 739 (1975). It is thus

inconceivable that Congress, against the backdrop of its attempts to curtail abusive securities class actions through the PSLRA and the Securities Litigation Uniform Standards Act of 1998 (SLUSA), Pub. L. No. 105-353, 112 Stat. 3227, would have created an open-ended limitation period, thereby exacerbating the problem of abusive securities litigation. By limiting stale lawsuits, Section 1658(b) acts as a check on the dangers that securities class actions pose to shareholders in particular and to the United States economy as a whole.

1. It is vital that the standard for triggering the running of the limitation period for securities actions be sufficiently rigorous to terminate stale securities class actions at the earliest stages of litigation, before discovery begins and the enormous pressure to settle starts to mount. Even outside the charged context of securities class actions, when a case that should have been barred moves beyond the motion-to-dismiss stage, the defendant is prejudiced in defending itself, because "[m]emories fade, documents are lost, [and] witnesses become unavailable." *Brumbaugh*, 985 F.2d at 162. Plaintiffs are thus better positioned to "coerce settlements simply because aging has improved an originally meritless claim." *Ibid.* Those concerns are even more real in securities class actions, as even suits with virtually no prospect of success can coerce significant settlements.

2. Meritless, abusive securities class actions impose a deleterious effect on the national economy. On average, securities class actions reduce a

defendant company's equity value by 3.5%. Anjan V. Thakor, *The Unintended Consequences of Securities Litigation* 14 (U.S. Chamber Institute for Legal Reform 2005), *available at* http://www.heartland.org/custom/semod_policybot/pdf/18330.pdf. Smaller companies, which are "the economy's engine for innovation and growth," suffer a disproportionate loss of equity value, in part because they are less able to achieve economies of scale in litigation costs. *Id.* at 9-10. Abusive securities litigation destroys far more of defendants' wealth than it creates for plaintiffs. *Id.* at 14.

Indeed, this Court has acknowledged that such actions destroy the value of the stock of innocent shareholders, rather than protecting their interests. *See Blue Chip Stamps*, 421 U.S. at 739 (costs associated with securities class actions are "payable in the last analysis by innocent investors for the benefit of speculators and their lawyers" (quoting *SEC v. Texas Gulf Sulphur Co.*, 401 F.2d 833, 867 (2d Cir. 1968) (Friendly, J., concurring))). Securities class actions often result only in "a transfer of wealth from current shareholders to former shareholders," and for those class members who are still shareholders at the time of suit, defendants' payments to plaintiffs "amount to transferring money from one pocket to the other, with about half of it dropping on the floor for lawyers to pick up." Janet Cooper Alexander, *Rethinking Damages in Securities Class Actions*, 48 Stan. L. Rev. 1487, 1503 (1996).

Abusive securities litigation also imposes burdens on the United States capital markets. Such litigation has been a driving force behind a growing perception that the United States legal system is more hostile for business than many of our international competitors, most notably the United Kingdom. *See* Michael R. Bloomberg & Charles E. Schumer, *Sustaining New York's and the US' Global Financial Services Leadership* ii (2007) ("Bloomberg-Schumer Report"). The result has been a rapid decline in the competitiveness of the United States capital markets, driven in large part by foreign firms' concerns over shareholder litigation in the United States. *See* Committee on Capital Markets Regulation, *Interim Report of the Committee on Capital Markets Regulation* x (2006). It is clear that "foreign companies [are] staying away from US capital markets for fear that the potential costs of litigation will more than outweigh any incremental benefits of cheaper capital." Bloomberg-Schumer Report at 101. The consensus is that "the prevalence of meritless securities lawsuits and settlements in the U.S. has driven up the apparent and actual cost of business—and driven away potential investors." *Id.* at ii.

And despite Congress's efforts to reign in abusive securities litigation by enacting the PSLRA and SLUSA, the clear trend is that the number of securities class action filings is rising. Comparing the two-year period from July 2005 to June 2007 with the period from July 2007 to June 2009, securities class action filings jumped by an astounding 60 percent.

See Cornerstone Research, *Securities Class Action Filings: 2009 Mid-Year Assessment*, at 3.

3. In addition to the costs imposed on the Nation's economy, abusive securities class action suits affect defendants in a way that is unique from other types of litigation. These class actions contain unique elements that encourage, if not compel, defendants to settle even the most insubstantial of claims. An overly generous reading of the statute of limitations would allow the pursuit of otherwise stale claims that should be time-barred and could result in billions of additional dollars of unwarranted settlements being extracted from the Nation's businesses.

If a securities class action moves into discovery, the legal costs of defending the suit impose an enormous burden on defendants. *See, e.g.*, James A. Kassis, *The Private Securities Litigation Reform Act of 1995: A Review of Its Key Provisions and an Assessment of Its Effects at the Close of 2001*, 26 Seton Hall Legis. J. 119, 124 (2001) (describing the discovery process as "financial blood letting"). Those costs are exponentially multiplied for stale cases, as the defendant must go even further back into document files and electronic archives and must dredge up forgotten memories of events that occurred more distantly in the past.

But the legal costs associated with abusive discovery are only one aspect of a broader problem. Depositions and other extensive discovery often draw the attention of key employees away from the

business's day-to-day operations and also its long-term strategies. Plaintiffs with "largely groundless claim[s]" can take advantage of liberal discovery rules "to simply take up the time of a number of other people," which represents a draining "social cost rather than a benefit." *Blue Chip Stamps*, 421 U.S. at 741.

The plaintiffs' bar is keenly aware of defendants' concerns about the enormous costs associated with securities class actions. They also know that securities class actions, with their potential for devastating damages awards, are high-stakes, bet-the-company litigation for any corporation. Thus, one of the key strategies of the plaintiffs' bar is to attempt to survive a motion to dismiss and then extract a large settlement. That is because "even a complaint which by objective standards may have very little chance of success at trial has a settlement value to the plaintiff out of any proportion to its prospect of success at trial so long as he may prevent the suit from being resolved against him by dismissal or summary judgment." *Blue Chip Stamps*, 421 U.S. at 740. Once a securities class action makes it past the motion-to-dismiss stage, "the mere existence of an unresolved lawsuit has settlement value to the plaintiff * * * because of the threat of extensive discovery and disruption of normal business activities which may accompany a lawsuit which is groundless in any event, but cannot be proved so before trial." *Id.* at 742-743.

So rather than focus on the merits of a securities class action, defendants often must settle such suits merely to avoid the prospect, no matter how unlikely, of potentially ruinous liability. Even a mere five percent chance of an adverse judgment in a class action alleging $1 billion in damages could make a $25 million settlement look attractive. And such a settlement could look even more palatable if the defendant's insurance will cover a portion of that amount. Indeed, empirical research has shown that the best predictors of whether a securities class action will be filed and what the ultimate settlement amount will be are the decline in stock price and the amount of the defendant's insurance coverage—two factors wholly divorced from the merits of the suit. Janet Cooper Alexander, *Do the Merits Matter? A Study of Settlements in Securities Class Actions*, 43 Stan. L. Rev. 497, 516-518 (1991).

The success of the settlement-extraction strategy by the plaintiffs' bar is evident. The past decade has seen an average of nearly 100 securities class action settlements each year. Total class action settlements over that time have averaged approximately $5.6 billion per year. Ellen M. Ryan & Laura E. Simmons, Cornerstone Research, *Securities Class Action Settlements: 2008 Review & Analysis*, at 1. In 2008, the trend of ever increasing securities class action settlement figures continued, with the median settlement coming in at $8 million, an eight percent increase over the median settlement for the prior nine years, even after adjusting for inflation. *Id.* at 2.

That success, in turn, encourages plaintiffs, and their counsel, to file even more suits. *See generally* John C. Coffee, Jr., *Understanding the Plaintiff's Attorney: The Implications of Economic Theory for Private Enforcement of Law Through Class and Derivative Actions*, 86 Colum. L. Rev. 669 (1986).

If anything, that trend demonstrates that a more lenient statute of limitations is entirely unnecessary to preserve meritorious claims. While, in general, a more stringent statute of limitations might preclude some meritorious claims, that is unlikely in the securities claim context if a plaintiff has two years after he is on notice of the possibility of fraud to file suit. In the experience of amicus and its members, the plaintiffs' bar files private securities class actions almost immediately upon the discovery of the smallest possibility of fraud—often within days or weeks of the plaintiff being placed on inquiry notice. Indeed, private securities fraud claims are often filed shortly after the SEC announces enforcement action (or another governmental agency releases a critical report, such as the FDA's warning letter in this case), and the private plaintiff generally simply repeats the allegations of the pending enforcement action. *See, e.g.*, *id.* at 682; Neil M. Gorsuch and Paul B. Matey, *Settlements in Securities Fraud Class Actions: Improving Investor Protection*, at 27 (2005), *available at* http://208.112.47.239/upload/0405WPG orsuch.pdf. Thus, if a private plaintiff does not file suit promptly upon inquiry notice, that likely has little (or

nothing) to do with any lack of ability to investigate the claim. Rather, it likely says more about the view of the plaintiffs' bar of the merit (or lack thereof) of the potential claim—and may even be a strategic attempt to game the market. The limitation period of Section 1658(b)(1) should not be read in a lax way that would make those claims—which are more likely to be abusive than to be meritorious—viable.

An open-ended statute of limitations, such as the one announced by the court below, should therefore be rejected, because it would make it more likely that otherwise stale claims would survive. That, in turn, would only further plaintiffs' ability to extract exorbitant settlements from amicus's members through abusive litigation and would encourage the filing of additional class actions, with their attendant burdens on innocent shareholders and the Nation's economy.

CONCLUSION

For the reasons set forth above and in petitioners' brief, the judgment of the court of appeals should be reversed.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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IN THE

Supreme Court of the United States

MERCK & CO., INC., *et al.*,
Petitioners,

v.

RICHARD REYNOLDS, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF *AMICI CURIAE* CHANGE TO WIN AND THE CHANGE TO WIN INVESTMENT GROUP IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Congress has provided in 28 U.S.C. §1658(b)(1) that private actions asserting violations of §10(b) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder, must be commenced within "2 years after the discovery of the facts constituting the violation." 28 U.S.C. §1658(b)(1). This Court holds that fraudulent intent or "scienter is an element of a violation of §10(b) and Rule 10b-5, regardless of the identity of the plaintiff or the nature of the relief sought." *Aaron v. SEC*, 446 U.S. 680, 691 (1980); *Basic Inc. v. Levinson*, 485 U.S. 224, 240 n.18 (1988) (quoting *Aaron*); *see Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 & n.12 (1976).

The question presented is whether, in light of this Court's holdings that a defendant's scienter is a fact essential to any violation of §10(b), and Congress' adoption of a limitations provision that by its terms commences only upon "the discovery of the facts constituting the violation," 28 U.S.C. §1658(b)(1), this Court should accordingly hold that the time to file §10(b) claims will not begin to run until a plaintiff possesses information from which it should infer that a defendant in fact acted with scienter.

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IN THE

Supreme Court of the United States

MERCK & CO., INC., *et al.*,
Petitioners,

v.

RICHARD REYNOLDS, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF *AMICI CURIAE* CHANGE TO WIN AND THE CHANGE TO WIN INVESTMENT GROUP IN SUPPORT OF RESPONDENTS

INTEREST OF *AMICI* [1]

Change to Win is an alliance of five unions with 5.5 million members, united to build a new movement of

[1] The parties consented to the filing of this *amicus* brief, by filing on July 20, 2009, a blanket consent to the filing of *amicus* briefs.

No counsel for any party authored this brief in whole or in part. No party or its counsel made any contribution to fund the preparation or submission of this brief. No person other than the *amici curiae*, their members, or their counsel, has made a monetary contribution to the preparation or printing of this brief.

Counsel for *amici* also represents plaintiff investors in a variety of pending cases involving the proper time for filing §10(b) claims, including *Alaska Electrical Pension Fund v. Pharmacia Corp.*, 554 F.3d 342 (3d Cir. 2009), *petition for cert. pending*, No. 08-1315 (filed Apr. 22, 2009).

working people that can meet the challenges of the global economy and restore the American Dream: a paycheck that can support a family, affordable health care, a secure retirement, and dignity on the job. The Change to Win partner unions are the International Brotherhood of Teamsters, Laborers' International Union of North America, Service Employees International Union, United Farm Workers of America, and the United Food and Commercial Workers International Union.

The Change to Win Investment Group was established to monitor corporate activity and protect the interests of Change to Win members who participate in Taft-Hartley plans with more than $200 billion in total assets. Because these funds are responsible for supporting the retirement benefits of their participants, they are diversified, are focused on long-term appreciation, and are particularly concerned with corporate-governance issues, including the prevention of securities fraud. These funds are the paradigmatic "institutional investors" to whom Congress has entrusted the presumptive leadership of private securities litigation. *See* 15 U.S.C. §78u-4(a)(3).

Change to Win and The Change to Win Investment Group filed *amicus* briefs in *Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148 (2008), and *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007), and have similarly supported the interests of its funds, workers, investors and shareholders before Congress and the Securities and Exchange Commission.

Amici have a strong interest in maintaining the right to assert claims for securities fraud in appropriate cases, and, in particular, in preventing claims from being prematurely barred by an unduly restric-

tive interpretation of the controlling statute of limitations. *Amici* believe that the time to file securities-fraud claims should not begin to run until facts showing fraud have come to light.

SUMMARY OF ARGUMENT

Section 1658(b) requires that any private litigant's claims for violation of §10(b) be filed within two years "after the discovery of the facts constituting the violation." 28 U.S.C. §1658(b)(1). This Court held in *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976), that investors must prove scienter to establish a §10(b) violation. And in *Aaron v. SEC*, 446 U.S. 680, 691 (1980), this Court held that "scienter is an element of a violation of §10(b) and Rule 10b-5, regardless of the identity of the plaintiff or the nature of the relief sought." *Id.* at 691; *see Basic Inc. v. Levinson*, 485 U.S. 224, 240 n.18 (1988) (quoting *Aaron*).

Yet petitioners and their *amici* all have somehow managed to overlook *Aaron's* critical holding, that without scienter there can be no violation of §10(b). Not one of them so much as cites *Aaron*. But if this Court's precedents and §1658's statutory text mean what they say, the two-year limitations period for filing §10(b) claims cannot commence until "after the discovery of the facts constituting the violation," 28 U.S.C. §1658(b)(1), including the fact of the defendant's scienter. *See Aaron*, 446 U.S. at 691.

If §1658(b) incorporates an inquiry-notice standard, the two-year period ought not begin to run until an objectively reasonable investor should have discovered facts showing that a defendant likely acted with scienter. Without facts indicating scienter, there is no reason for investors to think that §10(b) has been violated, and thus no reason to investigate further

the possibility of fraud. Thus, the fact that a company's statements were false or that an investment produced disappointment, without some indication of fraud, ought not place investors on duty of inquiry as a matter of law.

Where facts are sufficiently suggestive of fraud to place investors on a duty of inquiry, moreover, the controlling precedents indicate that potential plaintiffs may be charged only with knowledge of facts that their inquiry could reasonably be expected to uncover. And, where facts that should have been known or discovered are at issue, the burden is on the party asserting the statute of limitations defense to show what facts plaintiffs should have known or discovered. Yet Petitioners never say what reasonably diligent investors should have done in this case to uncover facts showing scienter that is not otherwise apparent.

Investors cannot be expected, before they discover facts showing fraudulent intent, to file suit in order to develop a hypothetical claim for fraud. Pleading rules applied by this Court in *Tellabs* preclude such a gambit. And inquiries directed to the company, or its officers, can hardly be expected to produce confessions. But if diligent inquiry cannot be expected to uncover facts showing fraud, there is no basis for imputing knowledge of facts amounting to fraud. And if Petitioners can explain neither what reasonably diligent Merck investors should have done to uncover facts demonstrating fraud, nor what they would have found, there is no basis for charging Merck investors with a failure of diligence.

The statute's plain meaning states a sound legal principle. Section 1658(b)(1)'s two years should run only upon "discovery of the facts constituting the

violation," including discovery of facts indicating that a defendant acted with scienter.

ARGUMENT

I. BY ITS PLAIN TERMS, §1658(b)(1)'S LIMITATIONS PERIOD COMMENCES ONLY UPON DISCOVERY THAT A DEFENDANT ACTED WITH SCIENTER

The two-year limitations period for filing §10(b) claims runs only upon "discovery of the facts constituting a violation," 28 U.S.C. §1658(b)(1), among the most critical of which is the fact that a defendant acted with scienter. Under this Court's holding in *Aaron*, "scienter is an element of a violation of §10(b) and Rule 10b-5, regardless of the identity of the plaintiff or the nature of the relief sought." *Aaron*, 446 U.S. at 691; *see Basic*, 485 U.S. at 240 n.18 (quoting *Aaron*). Without facts indicating scienter, then, there is no reason to suspect that §10(b) has been violated—and under an inquiry-notice standard, no duty to inquire further, let alone to file suit.

Enacted in 2002, by §804 of the Public Company Auditing Accountability and Responsibility Act, also known as the "Sarbanes-Oxley Act," 28 U.S.C. §1658(b) provides that any "private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement concerning the securities laws . . . may be brought not later than the earlier of—(1) 2 years after discovery of the facts constituting the violation; or (2) 5 years after such violation."[2] All agree that the provision is designed to cover private actions for violation of §10(b)

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[2] Pub. L. 107-204, Title VIII, §804(a), 116 Stat. 801, *codified as* 28 U.S.C. §1658(b).

of the Securities Exchange Act of 1934 ("Exchange Act" or "1934 Act"), which outlaws the use of "any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange] Commission may prescribe," 15 U.S.C. §78j(b), and of SEC Rule 10b-5 promulgated thereunder.[3] Rule 10b-5 "is coextensive with the coverage of §10(b)," *SEC v. Zandford*, 535 U.S. 813, 816 n.1 (2002), making it unlawful in connection with the purchase or sale of any security to employ "any device, scheme, or artifice to defraud," to make any untrue or misleading statements, or to engage in conduct that "operate[s] as a fraud." 17 C.F.R. §240.10b-5.

"The words 'manipulative or deceptive' used in conjunction with 'device or contrivance' strongly suggest that §10(b) was intended to proscribe knowing or intentional misconduct." *Ernst & Ernst*, 425 U.S. 197. The use of like words in §1658(b) similarly focuses on the element of intent essential to the claims that it governs.[4] Even more to the point, §1658(b)(1)'s provision that defrauded investors may sue within "2 years after discovery of the facts constituting the violation," on its face requires discovery of facts indicating that a defendant acted with scienter—since "scienter is an element of a violation of §10(b) and Rule 10b-5." *Aaron*, 446 U.S. at 691; *see Basic*, 485

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[3] *See In re Exxon Mobil Corp. Sec. Litig.*, 500 F.3d 189, 194-95 (3d Cir. 2007); *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 950 (9th Cir. 2005).

[4] *See Exxon Mobil*, 500 F.3d at 196-97 (finding §1658 does not apply to §14(a) claims for which scienter is not an element); *In re WorldCom, Inc. Sec. Litig.*, 294 F. Supp. 2d 431, 440-43 (S.D.N.Y. 2003), *rev'd on other grounds*, 496 F.3d 425 (2d Cir. 2007) (same regarding §11 claims).

U.S. 224 at n.18 (quoting *Aaron*). Under *Aaron*, an investor who has not discovered that a defendant acted with scienter has not discovered "the facts constituting the violation" of §10(b), as §1658(b)(1) plainly requires for its two-year limitations period to start running.

Petitioners nonetheless contend the court below somehow "*erred* by holding that a securities-fraud plaintiff is not on inquiry notice until he possesses information that the defendant acted with scienter." Pet. Brief at 14 (emphasis added). Section 1658(b)'s limitations period may run, they say, without regard to whether plaintiffs knew—or should have known—of any facts indicating fraudulent intent: "The language of Section 1658(b) supports such an approach," they insist, "because the better view is that the phrase 'facts constituting the violation' does not encompass the fact of scienter." Pet. Brief at 14-15.

Such contentions are flatly contrary to *Aaron's* holding. The Third Circuit put it succinctly in *Alaska Electrical Pension Fund v. Pharmacia Corp.*, 554 F.3d 342, 348 (3d Cir. 2009): "Scienter is not incidental to §10(b), it is elemental." Time and again, this Court has confirmed that §10(b) liability hinges upon the defendant's "*scienter*, *i.e.*, a wrongful state of mind." *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 341 (2005). "To establish liability under §10(b) and Rule 10b-5, a private plaintiff must prove that the defendant acted with scienter, 'a mental state embracing the intent to deceive, manipulate, or defraud.'" *Tellabs*, 551 U.S. at 319 (quoting *Ernst & Ernst*, 425 U.S. at 193-94 & n.12).

Section 1658(b)(1)'s two-year limitations period begins to run, by its terms, only upon "discovery of the facts constituting the violation" of §10(b). That

scienter is a fact can hardly be disputed. "The law has long recognized that a defendant's state of mind is not a 'subjective' matter, but a *fact* to be inferred from the surrounding circumstances." *Arave v. Creech*, 507 U.S. 463, 473 (1993) (Court's emphasis). As Lord Justice Bowen famously declared in the celebrated securities-fraud case of *Edgington v. Fitzmaurice*, 29 Ch. D. 459, 483 (C.A. 1885), "the state of a man's mind is as much a fact as the state of his digestion. It is true that it is very difficult to prove what the state of a man's mind at a particular time is, but if it can be ascertained it is as much a fact as anything else."[5]

This Court's precedents uniformly treat intent as a question of fact.[6] The principle that a defendant's state of mind is a fact, has been incorporated in our law of torts,[7] our law of contracts,[8] our criminal law,[9]

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[5] *See, e.g., Arave*, 507 U.S. at 473 (quoting Lord Justice Bowen's holding in *Edgington*); *United States Postal Service Bd. of Governors v. Aikens*, 460 U.S. 711, 716-17 (1983) (same); *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 744 (1975) (same); *Comm'r v. Culbertson*, 337 U.S. 733, 743 n.12 (1949) (same).

[6] *See, e.g., Sandstrom v. Montana*, 442 U.S. 510, 523 (1979); *United States v. United States Gypsum Co.*, 438 U.S. 422, 435 (1978); *Morissette v. United States*, 342 U.S. 246, 274 (1952) ("Where intent of the accused is an ingredient of the crime charged, its existence is a question of fact which must be submitted to the jury.").

[7] *See, e.g.*, Restatement (Second) of Torts §530, *Misrepresentation of Intention*, cmt. a ("The state of a man's mind is as much a fact as the state of his digestion."); *Palmacci v. Umpierrez*, 121 F.3d 781, 786 (1st Cir. 1997) (quoting same); W. Page Keeton, et al., *Prosser and Keeton on Torts* §109, at 762 (5th ed. 1984) (quoting Lord Bowen's holding in *Edgington*); Clarence Morris & C. Robert Morris, Jr., *Morris on Torts* 312 (2d ed. 1980) (same); 2 Fowler V. Harper, Fleming James, Jr. & Oscar S. Gray, *The Law of Torts* §7.8, at 427 n.11, §7.10, at 445 & n.10 (2d ed. 1986)

our civil-rights law,[10] and our regulatory law.[11] Thus, the leading treatise on our federal securities laws declares it "almost obligatory to quote Lord Bowen's observation."[12] In securities-fraud cases in particular, the appellate precedents hold that the defendant's scienter is a question of fact.[13] With the fact of

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("by the nineteenth century it had become a familiar notion that 'the state of a man's mind is as much a fact as the state of his digestion"; "[a]t least since the time Lord Justice Bowen penned his oft-quoted language the law has accepted a person's state of mind as a fact").

[8] Richard A. Lord, *Williston on Contracts* §69:42, at 65-66 (4th ed. 2003) (citing *Edgington*); Joseph M. Perillo, *Corbin on Contracts* §28.19, at 84-85 (Rev. ed. 2002) (quoting *Edgington*); John D. Calamari & Joseph M. Perillo, *The Law of Contracts* §9.19, at 334 (4th ed. 1998) (quoting *Edgington*); *accord* Restatement (Second) of Contracts §159 cmt. d, at 429 (1981) ("A person's state of mind is a fact . . . .").

[9] *See, e.g.*, *Arave*, 507 U.S. at 473.

[10] *See, e.g.*, *Aikens*, 460 U.S. at 716-17.

[11] *See, e.g.*, *United States v. Cello-Foil Prods.*, 100 F.3d 1227, 1233 (6th Cir. 1996) (quoting *Edgington* in assessing, for purposes of establishing CERCLA liability, parties' intent at contract formation).

[12] 7 Louis Loss & Joel Seligman, *Securities Regulation* 3416 (3d ed. 2003).

[13] *SEC v. Pirate Investor LLC*, 580 F.3d 233, 243 (4th Cir. 2009) (scienter is among the questions of fact such that a "'trial court's findings as to those facts may not be set aside unless they are clearly erroneous'") (quoting *Healey v. Chelsea Res. Ltd.*, 947 F.2d 611, 618 (2d Cir. 1991)); *In re Cerner Corp. Sec. Litig.*, 425 F.3d 1079, 1084-85 (8th Cir. 2005) ("Scienter is normally a factual question to be decided by a jury, but the complaint must at least provide a factual basis for its scienter allegations."); *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1113 (9th Cir. 1989) ("Materiality and scienter are both fact-specific issues which should ordinarily be left to the trier of the fact."); *SEC v. First Jersey Sec., Inc.*, 101 F.3d 1450, 1467 (2d Cir. 1996)

scienter essential to any violation of §10(b) and Rule 10b-5, *see Aaron*, 446 U.S. at 691, the two years provided by §1658(b)(1) can begin to run only upon "discovery of the facts constituting the violation," including the fact that a defendant acted with scienter.

II. THE CONCEPT OF "INQUIRY NOTICE" DOES NOT RELIEVE PETITIONERS OF THEIR BURDEN OF SHOWING WHEN AND HOW INVESTORS SHOULD HAVE DISCOVERED FACTS CONSTITUTING FRAUD

Without circumstantial evidence indicating that a defendant acted with scienter, there is no reason for investors to suspect a violation of §10(b), and no basis for requiring investors to inquire further. For scienter is the very *sine qua non* of fraud, such that without fraudulent intent *there can be no violation* of §10(b). *Aaron*, 444 U.S. at 691; *see Basic*, 485 U.S. at 240 n.18. Only once investors have been placed on a duty of inquiry by "storm warnings" indicating fraud may they be deemed to know what diligent inquiry would have uncovered.

The leading cases are clear: notice of facts that would compel an objectively reasonable investor to investigate further may trigger a duty of further reasonable inquiry. One who is thus placed on a duty of inquiry then may be charged with notice of what diligent inquiry would have disclosed—with the limitations period running from the time when discovery of facts constituting the claim fairly should have been made.

("Whether or not a given intent existed, is, of course, a question of fact.").

This Court has long held that in cases alleging claims of fraud, the time for suit "will not run in favor of the defendant until the discovery of the fraud, or until, with reasonable diligence, it might have been discovered." *Kirby v. Lake Shore & Michigan S. R.R.*, 120 U.S. 130, 136 (1887).[14] And under this "discovery rule," the time to sue cannot run in favor of defendants charged with fraud "until after such fraud was or should, with due diligence, have been discovered." *Id.* at 138. A plaintiff's time to sue thus runs only "'after he had knowledge of the fraud or after he was put on inquiry *with the means of knowledge accessible to him*.'" *Id.* at 139 (emphasis added) (quoting *Burke v. Smith*, 83 U.S. (16 Wal.) 390, 401 (1873)).

Applying this concept of inquiry notice to securities-fraud cases, "the discovery of fraud is either the date of actual discovery or the date on which the plaintiff . . . should have made such discovery." *Johns Hopkins Univ. v. Hutton*, 488 F.2d 912, 917 (4th Cir. 1973). Thus, "'"discovery" means either actual knowledge or notice of facts which, in the exercise of due diligence, would have led to actual knowledge of the violation.'" *Id.* at 917 (quoting *Azalea Meats v. Muscat, Inc.*, 386 F.2d 5, 8 (5th Cir. 1967)).

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[14] *See also Meader v. Norton*, 78 U.S. (11 Wal.) 442, 458 (1871) (the limitations period comes into play only "after the evidence of the fraud is discovered"); *cf. Railway Co. v. Sprague*, 103 U.S. 756, 762 (1881) (if an investor is presented with facts "sufficient to put her on inquiry, she can only be charged with knowledge of the facts which she might have learned by inquiry"). In *Veazie v. Williams*, 49 U.S. (8 How.) 134, 158 (1850), for example, this Court held that one induced by fictitious bids to an inflated price at auction, and who sought relief more than half a decade later, had "seasonably applied for relief, and should not be barred from obtaining it by any lapse of time while the fraud or mistake as to the bids not being real remained undiscovered."

Since the statute of limitations is an affirmative defense, *see* Fed. R. Civ. P. 8(c), on which defendants bear the burden of pleading and proof, this naturally requires defendants to demonstrate first that facts sufficiently probative of fraud came to plaintiff's attention such that they were compelled to make further inquiry, and second, how and when the reasonably diligent plaintiff should have found facts evidencing fraud.[15]

Yet disagreements about the interpretation of scientific results hardly amount to "storm warnings" of fraud. And even if they did, Petitioners must explain what investors should have done or found, before they may take advantage of the statute of limitations.

A. A Statement's Arguable or Even Actual Falsity Is Not, *Ipso Facto*, Sufficient to Place Investors on a Duty of Inquiry to Seek Facts Demonstrating Fraud

Simple falsity, or a disagreement about how to interpret data, cannot as a general rule be enough to trigger a duty of inquiry. The "discovery of the facts constituting the violation" of §10(b) requires more than a showing that investors should have been aware of a scientific dispute over the interpretation of study results, or that optimistic projections were not

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[15] *Young v. Lepone*, 305 F.3d 1, 9 (1st Cir. 2002) (where "a defendant seeks to truncate the limitations period by claiming that the plaintiff had advance notice of the fraud through the incidence of storm warnings, then the defendant bears the initial burden of establishing the existence of such warnings"); *Mathews v. Kidder, Peabody & Co.*, 260 F.3d 239, 252 (3d Cir. 2001) ("the burden is on the defendants to show the existence of 'storm warnings'").

realized, or even that statements were demonstrably false when made.

Disagreements about the interpretation of scientific studies do not usually involve—or even suggest—fraud.[16] That projections turn out to be wrong need not suggest fraud, and an investor's knowledge that financial predictions were "grossly incorrect" generally is "not sufficient to create notice inquiry as a matter of law."[17] Courts hold that even restatements *to*

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[16] *See Pharmacia*, 554 F.3d at 350 & n.7; *Nathenson v. Zonagen Inc.*, 267 F.3d 400, 420 (5th Cir. 2001) ("'Medical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols.'"); *In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 930 (9th Cir. 1996) (finding no misrepresentation where, although defendants were aware of disagreements with the FDA at the time statements were made, they could have believed in good faith that disagreements would be resolved); *LaSalle v. Medco Research*, 54 F.3d 443, 446 (7th Cir. 1995) (recall of drug company's main product indicated difficulty obtaining FDA approval, but did not suggest fraud); *In re Medtronic Inc., Sec. Litig.*, 618 F. Supp. 2d 1016, 1029 (D. Minn. 2009) (alleged "inadequacy" of data relied on by defendants was insufficient to establish fraud); *In re Sepracor, Inc. Sec. Litig.*, 308 F. Supp. 2d 20, 36 (D. Mass. 2004) (defendants' statement that testing was "state of the art" did not raise inference of scienter where there was no FDA-approved testing method); *In re PLC Systems, Inc. Sec. Litig.*, 41 F. Supp. 2d 106, 121 (D. Mass. 1999) (noting that "[t]he securities laws do not impose a duty to conduct 'good science'"); *In re Medimmune, Inc., Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Medical researchers may well differ over the adequacy of given testing procedures and in the interpretation of test results.").

[17] *Sudo Properties Inc. v. Terrebonne Parish Consol. Gov't*, 503 F.3d 371, 377 (5th Cir. 2007); *see also In re Ames Dep't Stores, Inc. Note Litig.*, 991 F.2d 968, 981 (2d Cir. 1993) (press release reporting profit shortfall and lower-than-expected sales was insufficient to place noteholders on notice of fraud).

correct errors in a company's reported financial results need not indicate fraud,[18] or place investors on inquiry notice.[19] Neither do most business failures involve fraud—however surprised and disappointed investors may be.[20] Thus, even a stock's dramatic collapse on

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[18] *See, e.g., Horizon Asset Management Inc. v. H&R Block, Inc.*, 580 F.3d 755, 764-65 (8th Cir. 2009) (company's swift corrective actions including disclosure of deficiencies in internal controls and need to issue corrected financial statements held to undermine hypothetical inference of scienter); *Matrix Capital Management Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 183 (4th Cir. 2009) (restatement attributed to "incompeten[t]" former senior management held not to demonstrate intentional wrongdoing); *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1000 (9th Cir. 2009) ("the mere publication of a restatement is not enough to create a strong inference of scienter").

[19] *See Newman v. Warnaco Group, Inc.*, 335 F.3d 187, 194 (2d Cir. 2003) (restated financial results did not place investors on inquiry notice for §10(b) claims because they "did not contain *any* indication that fraud was being perpetrated") (court's emphasis).

[20] *See Pharmacia*, 554 F.3d at 349 ("mere investor disappointment does not *ipso facto* imply fraud"); *Livid Holdings*, 416 F.3d at 951 (bankruptcy filing insufficient to effect inquiry notice as to §10(b) claims as a matter of law); *Gray v. First Winthrop Corp.*, 82 F.3d 877, 881 (9th Cir. 1996) ("It is well settled that poor financial performance, standing alone, does not necessarily suggest securities fraud at the time of the sale, but could also be explained by poor management, general market conditions, or other events unrelated to fraud, creating a jury question on inquiry notice."); *Breen v. Centex Corp.*, 695 F.2d 907, 912 (5th Cir. 1983) (poor financial performance, which could be attributed to a "myriad of reasons," did not place plaintiffs on notice of fraudulent conduct); *see also Garvin v. Greenbank*, 856 F.2d 1392, 1399-1400 (9th Cir. 1988) ("'There is nothing illegal about a business failing . . . . The bankruptcy courts consider thousands of such unfortunate occurrences.'") (quoting *State v. Bridgeforth*, 156 Ariz. 60, 64, 750 P.2d 3, 7 (Ariz. 1988)); *cf.*

news that dashes investors' expectations will not ordinarily place them on inquiry notice of fraud—not as a matter of law, at any rate.[21]

Even an objectively false statement may be uttered without fraudulent intent—negligently or perhaps innocently. Indeed, Congress determined the issuer of securities should be held strictly liable under §11 of the Securities Act of 1933 even for *innocent* misstatements or omissions affecting a newly issued security's registration statement.[22]

Robert S. Adler, *Flawed Thinking: Addressing Decision Biases in Negotiation*, 20 Ohio St. J. Disp. Resol. 683, 726 & n.162 (2005) (noting "that most new businesses fail within a few years," and citing a study by the Small Business Administration's Office of Advocacy "indicating that between 1989 and 1992, only 39.5% of new business starts remained open after six years").

[21] *See Pharmacia*, 554 F.3d at 349 ("the drop in stock price . . . of February 6-8, 2001 did not indicate fraud or even the possibility of fraud"); *La Grasta v. First Union Sec., Inc.*, 358 F.3d 840, 847 (11th Cir. 2004) ("There may be numerous reasons, other than fraud, for a stock to decline (even steeply) in price."); *La Salle*, 54 F.3d at 446 (7th Cir. 1995) (declining to find investors were placed on inquiry notice by stock drop, because "[w]hat goes up fast sometimes comes down fast—without fraud"); *Mosesian v. Peat, Marwick, Mitchell & Co.*, 727 F.2d 873, 877-78 (9th Cir. 1984) (stock's rapid decline from $26.25 to $7.125 insufficient to trigger inquiry notice as a matter of law); *SEC v. Seaboard Corp.*, 677 F.2d 1297, 1304 (9th Cir. 1982) (95% decline in securities' value did not place investors on notice of fraud as a matter of law); *Briskin v. Ernst & Ernst*, 589 F.2d 1363, 1368 (9th Cir. 1978) (a missed dividend, 85% decline in stock value, and documents showing a "shortage of capital and increasing debt" insufficient to place investors on inquiry notice of fraud as to misrepresentations of financial condition made in connection with a merger).

[22] This Court has held:

Under the governing limitations provisions, this difference between §11 claims and §10(b) claims affects the time to sue. As amended in 1934, §13 of the 1933 Act requires an action under §11 for innocent or negligent misstatements in a registration statement to be "brought within one year after the discovery of the untrue statement or the omission, or after such discovery should have been made by the exercise of reasonable diligence," 15 U.S.C. §77m, without regard to facts bearing upon any defendant's state of mind. But the two-year time for filing a *fraud* claim under §10(b) runs from "discovery of the facts constituting the violation," 28 U.S.C. §1658(b)(1), which requires scienter. *See Aaron*, 446 U.S. at 691. Section

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> If a plaintiff purchased a security issued pursuant to a registration statement, he need only show a material misstatement or omission to establish his *prima facie* case. Liability against the issuer of a security is virtually absolute, *even for innocent misstatements*. Other defendants bear the burden of demonstrating due diligence.

Herman & MacLean v. Huddleston, 459 U.S. 375, 382 (1983) (emphasis added); *accord Ernst & Ernst*, 425 U.S. at 208 ("the issuer of the securities is held absolutely liable"); *see In re NationsMart Corp. Sec. Litig.*, 130 F.3d 309, 314 (8th Cir. 1997).

A House Report underscored the importance of imposing liability without a showing of fault on the issuer's part given the fact that scienter would seldom be apparent even in cases of deliberate wrongdoing:

> Every lawyer knows that with all the facts in the control of the defendants it is practically impossible for a buyer to prove a state of knowledge or a failure to exercise due care on the part of defendant. Unless responsibility is to involve merely paper liability it is necessary to throw the burden of disproving responsibility for reprehensible acts of omission or commission on those who purport to issue statements for the public's reliance.

H. Rep. No. 73-85, 1st Sess., at 9-10 (1933).

1658(b)(1), thus restates the standard of 1934 Act §9(e), 15 U.S.C. §78i(e), which was adopted by this Court in *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350, 364 n.9 (1991).

In *Law v. Medco Research*, 113 F.3d 781, 786 (7th Cir. 1997), the Seventh Circuit observed that when an investor asserts a §11 claim because a security's registration statement contained a false statement, "all he has to know is that the statement was untrue; so, as soon as he knows or should know that, the one-year period [of §13] begins to run." *Id.* at 785-86. "In a fraud case," under 1934 Act §10(b), however, "he needs to know more: that the defendant has made a representation that was *knowingly* false." *Id.* at 786 (court's emphasis). "When the plaintiff knows or should know this, the statute of limitations begins to run." *Id.*

"This approach is implied in *Lampf* itself," the Seventh Circuit observed, when this Court said that equitable tolling was "unnecessary" under a discovery rule it described "as requiring that suit be 'commenced within one year after the discovery of the *facts constituting the violation*.'" *Id.* at 786 (court's emphasis).

The Third Circuit held similarly in *Pharmacia*, that "inquiry notice, in securities fraud suits, requires storm warnings indicating that defendants acted with scienter." 554 F.3d at 348.

> Accordingly, for investors to be on inquiry notice of §10(b) claims, there must be some indication that defendants did not, in fact, hold the views expressed. Inquiry notice requires storm warnings of "culpable activity." Under §10(b), a corporation does not engage in culpable activity

> unless it acted with scienter. Scienter is not incidental to §10(b), it is elemental.

Id. (citations omitted).

Knowledge that a defendant's statements were controversial or factually inaccurate does not amount to notice of fraud absent a reason to believe that the statements were *knowingly* or *recklessly* wrong.[23]

Courts take a similar approach when dealing with analogous issues under state law. Alaska's Supreme Court, for example, recognized the dichotomy between claims for fraud, and claims for merely negligent misrepresentation, when it held in *City of Fairbanks v. Amoco Chem. Co.*, 952 P.2d 1173 (Alaska 1998), that the plaintiff's "knowledge of a misrepresentation does not necessarily also provide evidence of the defendant's scienter—*i.e.*, evidence that the defendant intended to misrepresent—even though it triggers the running of the limitations statute for negligent misrepresentation." *Id.* at 1180. Alaska's Supreme Court held "the *plaintiff's* knowledge of the inadequacy of a product or belief that there were inaccurate

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[23]*See Law*, 113 F.3d at 786; *Pharmacia*, 554 F.3d at 348; *accord, e.g.*, *Sudo Properties*, 503 F.3d at 377 (investor not on inquiry notice of §10(b) claims without information indicating he had been *deliberately* misled); *In re Motorola Sec. Litig.*, 505 F. Supp. 2d 501, 537 n.40 (N.D. Ill. 2007) (finding summary judgment inappropriate "because investors were not aware of facts indicating *scienter*" until after class period ended, and stating "[t]here is nothing inconsistent about the market reacting sharply to disclosures of truth . . while remaining unaware that [d]efendants had acted with allegedly fraudulent intent in concealing that information previously"); *Nappier v. PricewaterhouseCoopers LLP*, 227 F. Supp. 2d 263, 268, 274-75 (D.N.J. 2002) (statute did not bar plaintiffs' claims where they discovered evidence against auditor more than two years after the close of the class period).

representations does not prove the state of the *defendant's* mind when the defendant made representations about the product's properties." *Id.* at 1179 (court's emphasis).

City of Fairbanks notes the Ninth Circuit's decision in *Nevada Power Co. v. Monsanto Co.*, 955 F.2d 1304, 1308 (9th Cir. 1992), as one that similarly "distinguishes between knowledge of a false representation (an element in both fraud and negligent misrepresentation claims), and knowledge of the defendant's state of mind (an element of a fraud claim not also required for negligent misrepresentation)." *City of Fairbanks*, 952 P.2d at 1177. In *Nevada Power*, whose holding Nevada's Supreme Court cites with approval,[24] the Ninth Circuit reversed summary judgment on a state-law claim subject to Nevada's three-year limitations period for fraud. Although the *falsity* of the defendants' statements was known to the plaintiff eleven years before filing suit, it could have reasonably inferred from facts then available that the misstatements at issue were the consequence of the defendants' ignorance—rather than the willful cover-up that was much later exposed. *Nevada Power*, 955 F.2d at 1308. As such, the limitations period of claims *for fraud* began to run only when the plaintiff learned that the statements at issue had been *knowingly* false when made. *Id.*

Many cases similarly hold that a plaintiff's awareness of an injury and its cause, which may trigger the limitations period for other non-fraud claims, does not place that plaintiff on inquiry notice of fraud. Thus, in *Snow v. A.H. Robins Co.*, 165 Cal. App. 3d

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[24] *See, e.g., Siragusa v. Brown*, 114 Nev. 1384, 1400-01, 971 P.2d 801, 812 (Nev. 1998); *Bemis v. Estate of Bemis*, 114 Nev. 1021, 1025, 967 P.2d 437, 440 (Nev. 1998).

120, 211 Cal. Rptr. 271 (Cal. Ct. App. 1985), the fact that a woman knew the defendant's Dalkon Shield intrauterine device had failed, subjecting her to an unwanted pregnancy, operated to bar only non-fraud claims. "Her cause of action for fraud would not accrue until she became aware of facts from which she could conclude that defendant may have fraudulently misrepresented or concealed the *actual* risk of pregnancy with the Dalkon Shield." *Snow*, 165 Cal. App. 3d at 134, 211 Cal. Rptr. at 279 (court's emphasis). Similarly, in *Bodunov v. Kutsev*, 214 Ore. App. 356, 164 P.3d 1212 (Ore. Ct. App. 2007), the fact that the purchaser of real estate learned that the sellers' representations concerning the legality of uses to which the property was being put had been false when made did not constitute notice of fraud—the statute did not begin to run until the purchaser *also* learned that the sellers' statements were *knowingly* false. *Bodunov*, 214 Ore. App. at 364-65, 164 P.3d at 1217-18.

In *Burr v. Board of County Commissioners of Stark County*, 23 Ohio St. 3d 69, 491 N.E.2d 1101 (Ohio 1986), a couple's suit for wrongful adoption based on fraudulent misrepresentations of the child's good health was not barred by the statute of limitations—even though the adoptive parents knew the child suffered from developmental and cognitive disabilities 18 years prior to filing suit. For the couple did not learn that the adoption agency's statements were *deliberately* false until they sought and obtained previously-sealed court records regarding the child's health history. *Burr*, 23 Ohio St. 3d at 76, 491 N.E. 2d at 1108.

In *O'Hara v. Kovens*, 305 Md. 280, 503 A.3d 1313 (Md. 1986), plaintiffs alleged they had sold stock at a

price artificially depressed by Governor Marvin Mandel's veto of legislation, which they contended was part of a fraudulent scheme. Maryland's highest court noted that because "notice must relate to the fraud alleged," it necessarily included notice of "the state of mind of Governor Mandel," who had "misrepresented the true reasons for the veto, which had been cast to depress Marlboro stock, not simply incidentally, but for the purpose of benefiting co-conspirators as future stock purchasers." *O'Hara*, 305 Md. at 303, 503 A.2d at 1324. Extensive press coverage of Mandel's veto, and his curious failure to oppose an override, did not trigger inquiry notice—only discovery of facts demonstrating the Governor's fraudulent intent could do that. *See id.*

Discovery of a false statement or omission, and discovery of a violation involving scienter, are two different things. The difference is critical. Congress determined that the time to sue for a 1933 Act claim should run from when investors either discover, or in the exercise of reasonable diligence should have discovered, that offering documents were false or misleading. 15 U.S.C. §77m. Fraud-based claims should run only "after the discovery of the facts constituting the violation," including the defendant's culpable state of mind. *See* 15 U.S.C. §78i(e); 28 U.S.C. §1658(b)(1). And investors should be able to presume that corporate fiduciaries generally act in good faith.

B. The Statute Should Not Begin to Run Until Investors Should Know They Have a Claim

Petitioners never explain what objectively reasonable investors should be required to do, let alone when they should have found facts constituting a violation of §10(b). They simply assume that every reasonable

investor knew (or should have known) everything that was knowable about Merck. That is, quite simply, not the law. Notice of records, even of records that might themselves be subject to judicial notice, cannot be imputed willy nilly, without regard to whether litigants were under some duty—in the first place—to search those records out.[25] Circuit courts have many times rejected ill-grounded contentions that investors—who as yet have no reason to search

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[25] *See Fujisawa Pharmaceutical Co. v. Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997) ("[M]ore than bare access to necessary information is required to start the statute of limitations running. There must also be a suspicious circumstance to trigger a duty to exploit the access; an open door is not by itself a reason to enter a room."); *Great Rivers Coop. v. Farmland Industries*, 120 F.3d 893, 896 (8th Cir. 1997) (to assess whether plaintiff was on inquiry notice, court must determine whether, in light of facts known to plaintiff, a reasonable investor would have investigated further); *Nettles v. Childs*, 100 F.2d 952, 957 (4th Cir. 1939) ("the law imputes knowledge when opportunity and interest, coupled with reasonable care, would necessarily impart it; and if a person has actual knowledge of facts which would lead an ordinarily prudent man to make further investigation, the duty to make inquiry arises and the person is charged with knowledge of the facts which inquiry would have disclosed"); *see also Bemis*, 114 Nev. at 1026, 967 P.2d at 441 (rejecting contentions that, for purposes of the statute of limitations, children of divorced parents "should have known of their parents' divorce agreement simply because it was public record"); *Hobart v. Hobart Estate Co.*, 26 Cal. 2d 412, 442, 159 P.2d 958, 974 75 (Cal. 1945) ("In the absence of a duty to make inquiry . . . the statute does not run merely because the means of discovery were available"); *Tarke v. Bingham*, 123 Cal. 163, 166, 55 P. 759, 760 (Cal. 1898) ("[T]he mere fact that means of knowledge are open to a plaintiff and he has not availed himself of them, does not debar him from relief when thereafter he shall make actual discovery. The circumstances must be such that the inquiry becomes a duty, and the failure to make it a negligent omission.").

for it—may be automatically charged with knowledge of information simply because it could be found in some corner of the public domain had they some reason to seek it out.[26]

Petitioners and their *amici* seem to assume that the objectively reasonable investor is an institution purchasing actively traded securities and employing plaintiff's class-action lawyers to investigate every

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[26] *See, e.g., Great Rivers Coop.*, 120 F.3d at 897 (refusing to impute automatically public information to a securities-fraud plaintiff); *Smith v. Duff & Phelps, Inc.*, 891 F.2d 1567, 1571 (11th Cir. 1990) (specifically rejecting contentions that because the plaintiff "read the *Wall Street Journal*, he should have seen the articles" dealing with his investment); *Kronfeld v. Trans World Airlines, Inc.*, 832 F.2d 726, 736 (2d Cir. 1987) ("There are serious limitations on a corporation's ability to charge its shareholders with knowledge of information omitted from a document such as a proxy statement or prospectus on the basis that the information is public knowledge and otherwise available to them."); *Rochelle v. Marine Midland Grace Trust Co.*, 535 F.2d 523, 532 (9th Cir. 1976) (refusing to impute knowledge of publicly available information absent media coverage so not "massive" as to foreclose the possibility that the plaintiff was unaware of it); *Sperry v. Barggren*, 523 F.2d 708, 711 (7th Cir. 1975) (reversing district court that entered summary judgment based on "news items, two of which appeared only in Wisconsin papers, without considering the lack of any factor which might have alerted an average shareholder residing in Florida to be wary"); *cf. Briskin*, 589 F.2d at 1367 (Rejecting contentions that investors were on notice of the contents of publications *to which they actually subscribed*: "Knowledge of the paper's contents could not be conclusively imputed to the subscribers before the date they saw it unless a court can say as a matter of law that a reasonably prudent person will read all trade papers on the date they were received."); *see also Deveny v. Entropin, Inc.*, 139 Cal. App. 4th 408, 42 Cal. Rptr. 3d 807 (Cal. Ct. App. 2006) (declining to find that information posted on defendant's website placed investors on notice of that information as a matter of law).

downturn in any of its investments. Yet the standard the Court articulates must be one that applies to *all* investors. Some §10(b) claims are filed by individual investors cheated by their stockbroker or investment manager.[27] Some are filed by investors in private placements and limited partnerships.[28]

Even where the case is a class action alleging a fraud on the market of an actively traded security, *e.g.*, *Basic*, 485 U.S. 224, the class of investors may include literally thousands of individual investors as well as professionals and institutions. Thus, the standard to be applied in such a class action should be one that makes as much sense when applied to a retired school teacher in Boca Raton, with a portfolio of fifteen or twenty stocks in her 401(k), as it does when applied to a modest labor-union pension fund,

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[27] *See, e.g.*, *Dean Witter Reynolds v. Byrd*, 470 U.S. 213, 214 (1985) (retired dentist sued broker-dealer); *Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 871 (9th Cir. 2008) (suit by retiree who entrusted her life savings to an investment management firm), *petition for cert. pending*, No. 07-1489 (filed May 27, 2008); *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1566 (9th Cir. 1990) (en banc) ("Emil Wilkowski, a dishonest securities salesman, embezzled money entrusted to him by four clients."); *Jensen v. Snellings*, 841 F.2d 600, 603 (5th Cir. 1988) (husband and wife sued their attorney, broker, and the company in which they were induced to invest); *see also Zandford*, 535 U.S. at 815 (SEC civil-enforcement action where "a stockbroker violated both §10(b) . . . and the SEC's Rule 10b-5, by selling his customer's securities and using the proceeds for his own benefit").

[28] *See Marks v. CDW Computer Centers*, 122 F.3d 363, 365 (7th Cir. 1997) (employee and minority shareholder in closely held corporation); *Brumbaugh v. Princeton Partners*, 985 F.2d 157, 159 (4th Cir. 1993) (individual investor in limited partnership); *Ritchey v. Horner*, 244 F.3d 635, 637 (8th Cir. 2001) (individual purchasers of family-owned corporation).

or to a large institution. The retired teacher cannot be expected to read every press release or newspaper article dealing with the companies whose stock she owns, let alone to monitor regulatory agencies' websites and court filings. With tens of millions of lawsuits filed annually, investors cannot possibly be tasked with finding and reviewing every pleading that perhaps touches upon their investments.

Few sophisticated investors—if any—undertake such a detailed program of monitoring of their holdings. Pension funds, in particular, must conserve their resources, and watch their expenses.

Petitioners' *amici* declare that some institutional investors employ plaintiffs' attorneys to monitor their portfolios for signs of trouble. Even if some investors do take such precautions, a *rule* that *every* objectively reasonable investor is obligated to do so—though perhaps attractive to the plaintiffs' class-action bar—lacks sound foundation in existing law and precedent.

Even assuming that some investors were actually confronted with facts that should have given them concern, Petitioners never explain what steps reasonable diligence required of them. Petitioners have done even less to suggest what diligence should have entailed, and what it might have unearthed, than did defense counsel in *Law* who "suggested that the plaintiffs should have hired a lawyer to investigate, called their broker, or called Medco." 113 F.3d at 786. "These do not," wrote Judge Posner for the Seventh Circuit, "strike us as serious suggestions." *Id.*

What, in this case, should reasonable investors have done upon hearing that the FDA thought Merck's statements could be misleading, too one-sided, or because its naproxen hypothesis was too speculative?

They cannot reasonably be expected to undertake their own scientific studies to verify or invalidate the hypothesis—and had they done so, even a study that negates a hypothesis would not demonstrate that the hypothesis had been advanced in bad faith and with a fraudulent intent.

So what was each of Merck's many thousands of investors supposed to do in order to demonstrate reasonable diligence? Should they have written letters to Merck asking if the naproxen hypothesis had been adopted in bad faith? Could such letters be expected to turn up evidence of fraud? Surely not.

Investors and their lawyers could not file suit in hopes of developing evidence to support hypothetical claims of fraud. Investors must have enough evidence to plead a case *before* they file suit. *See* 15 U.S.C. §78u-4(b)(3)(B); *Fujisawa*, 115 F.3d at 1335.

In fact, Petitioners' arguments appear to produce an absurd "Cath-22." Petitioners say the limitations period must begin to run without regard to whether a potential plaintiff has any evidence of scienter. Yet the pleading requirements applied in *Tellabs* require dismissal if investors cannot at the outset "state with particularly facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C §78u-4(b)(2). Thus investors who, without evidence producing a strong inference of potential defendants' scienter cannot yet state a claim for fraud, could under Petitioners' construction of §1658(b)(1) find that meritorious claims for deliberate fraud are already barred as untimely by the time evidence of wrongdoing *first comes to light*. This cannot be what Congress intended when it provided that claims may be filed within "2 years

after discovery of the facts constituting the violation." 28 U.S.C. §1658 (b)(1).

If, when all is said and done, Petitioners can point to *nothing* that investors *should have* done to investigate the possibility of fraud, then it makes no sense to charge Merck investors with a failure of diligence. If Petitioners cannot point to evidence that reasonable diligence would have turned up, then it is hard to see how investors may be charged with notice of hypothetical information *that not even Petitioners can identify*.

The Court should hold they have not carried their burden of demonstrating an affirmative defense.

CONCLUSION

For all the foregoing reasons, the decision below should be affirmed.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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MERCK & CO., INC., *et al.*,

Petitioners,

—v.—

RICHARD REYNOLDS, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE CONNECTICUT RETIREMENT PLANS AND TRUST FUNDS, LOS ANGELES COUNTY

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October 26, 2009

EMPLOYEES RETIREMENT ASSOCIATION, THOMAS P. DINAPOLI, COMPTROLLER OF THE STATE OF NEW YORK, AS TRUSTEE OF THE NEW YORK STATE COMMON RETIREMENT FUND AND AS ADMINISTRATIVE HEAD OF THE NEW YORK STATE AND LOCAL RETIREMENT SYSTEMS, PENNSYLVANIA PUBLIC SCHOOL EMPLOYEES' RETIREMENT SYSTEM, THE PENNSYLVANIA STATE EMPLOYEES' RETIREMENT SYSTEM AND THE GENERAL TREASURER OF THE STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

(*List of parties continued*)

and as Administrative Head of the New York State and Local Retirement Systems, Pennsylvania Public School Employees' Retirement System, Pennsylvania State Employees' Retirement System and the General Treasurer of the State of Rhode Island and Providence Plantations

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INTEREST OF AMICI CURIAE

This *amicus* brief is filed on behalf of public pension systems that serve as fiduciaries to public employees who rely on them to prudently manage their retirement funds.[1] These public funds have a special responsibility to help insure the accountability of participants in the securities markets, and therefore a strong interest in the integrity of, and eliminating fraud in, such markets. Together, the *amici* public pension funds invest an aggregate over $235 billion in the capital markets for over 2.1 million active and retired beneficiaries.[2] The *amici* believe that Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and the limitations period for bringing claims thereunder, should be interpreted to achieve Congress's intent to provide redress for misrepresentations and deceptive practices in purchases and sales of securities, while at the same time eliminating premature and vexatious litigation.

The *amici's* overriding responsibility is to provide for the payment of benefits to their members and, in doing so, to invest for the long-term security of their millions of active and retired members. As major

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[1] This brief was not authored, in whole or in part, by counsel for either party, and no person or entity other than *amici* and their counsel contributed monetarily to the preparation or submission of the brief. The parties' blanket consent to the filing of *amicus* briefs was lodged with the Clerk of the Court on July 20, 2009.

[2] According to the US Census Bureau's 2009 Statistical Abstract, state and local retirement funds had $3.152 trillion in assets in 2007 ($1.98 trillion in corporate equities). U.S. CENSUS BUREAU, ASSETS, OF PRIVATE AND PUBLIC PENSION FUNDS (2009), http://www.census.gov/compendia/statab/tables/09s1177.xls.

investors with long-term outlooks, the *amici* are vitally concerned with the proper and efficient functioning of U.S. capital markets and are concerned that investors not be harmed by fraudulent conduct. Many state and local governments are constitutionally obligated to guarantee defined benefit retirement plans. Therefore, investment losses due to securities fraud fall directly on state and local governments, and ultimately, on taxpayers. If public pension funds are prevented from recovering money lost to securities fraud, the public will suffer.[3]

In recent years, public pension funds have become increasingly concerned about the integrity of U.S. securities markets. Scandals at Enron, WorldCom, Global Crossing, Tyco, Refco, Fannie Mae, Freddie Mac, Adelphia, Xerox, and numerous other public companies have caused hundreds of billions of dollars in losses to innocent investors. As investors who have been materially harmed by corporate fraud, the *amici* have strong interests in ensuring that the law allows injured investors to recover from perpetrators of fraud.

The *amici* strongly believe that investors' ability to redress corporate wrongdoing through private actions under the Securities Exchange Act of 1934 is essential to deter improper conduct and to recoup losses caused by fraud. Indeed, with the enactment of the Private Securities Litigation Reform Act, Pub. L. 104-67, 109 Stat. 737 ("PSLRA"), Congress sought "to increase the likelihood that institutional investors will serve as lead plaintiffs," based on its belief "that

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[3] From 2004 to 2007, investment earnings (as opposed to worker or government contributions) constituted between 74 and 82 percent of public pension funding. *See* http://www.ebri.org/pdf/notespdf/EBRI_Notes_04-Apr09.PblcPnsPlns1.pdf.

increasing the role of institutional investors in class actions will ultimately benefit shareholders and assist courts by improving the quality of representation in securities class actions." H.R. Conf. Rep. 104-369, 1995 U.S.C.C.A.N. 730, 732.

While the *amici* are vitally concerned that redress for securities fraud be available, as significant investors in thousands of corporations that never have been touched by even a taint of fraud, the *amici* also have a strong interest in ensuring that such innocent corporations are not subject to premature securities fraud claims and the expenses required to defend such claims. Because adoption of the Petitioners' arguments will result in the filing of premature lawsuits that may never become fully ripe, the *amici* are submitting this brief to assist this Court in developing rules that adequately protect both investors and companies. The *amici* are also concerned that the legal regime foster investors' trust in management and not require investors to disregard or disbelieve, without significant reason, statements by management regarding issues of significance to the corporation.

SUMMARY OF ARGUMENT

The *amici* support the Respondents and believe that the decision of the Third Circuit in *In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 543 F.3d 150 (3d Cir. 2008), *cert. granted*, 129 S. Ct. 2432 (2009) should be affirmed. The Third Circuit articulated a two-part test to determine when the two-year period begins to run based on inquiry notice. Under the first part, the Court addressed whether the plaintiffs had sufficient information of possible wrongdoing to place them on "inquiry notice" or to

excite "storm warnings" of culpable activity to initiate the running of the statute, and under the second part, whether the limitations period should not be deemed to have started because there was a basis upon which plaintiffs could claim that they were unable to discover their injuries. *See Merck*, 543 F.3d at 161. Addressing the first prong (the second prong was not addressed by the Court), the Third Circuit articulated an inquiry notice standard in securities fraud actions, which requires "sufficient information to suspect that the defendants engaged in culpable activity," before the statute of limitations begins to run.[4] This standard is consistent with the plain language of the statute, comports with Congressional intent, and strikes the proper balance among competing policy concerns, namely, the interests in curbing frivolous, premature and poorly-pled lawsuits, while at the same time ensuring that violators of the securities laws do not escape liability, as well as the need to ensure that corporate defendants are not subject to stale lawsuits.

It is the *amici's* position that injured investors should have access to information concerning each of the core elements of a securities fraud action (false statement, scienter and damages) in order to start the running of the statute of limitations. Thus,

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[4] Petitioners repeatedly attempt to conflate these two steps so as to impose on plaintiffs the burden of investigating any misstatement even in the absence of sufficient information to suggest culpable activity, and thus advance a standard of inquiry notice that would trigger the statute of limitations based on mere suspicion. Pet. Br. at 13, 22. *Amici* herein address only the standard and information sufficient to trigger the running of the statute of limitations; the *amici* are not addressing the second part of the Third Circuit's two-part test or the standard and quantum of information sufficient to trigger a duty to investigate.

a misstatement, in and of itself, is not sufficient to trigger the statute. Plaintiffs should not be compelled to initiate litigation following a mere misstatement, absent some indication that it was intentionally false.

In recent years, Congress recognized the complexities of securities fraud and specifically amended the statute of limitations to allow defrauded investors adequate time to prepare a complaint that would meet the heightened pleading standards under the PSLRA. Petitioners attempt to subvert Congress's intent and undermine the purposes of the extended limitations period by asking this Court to adopt an inquiry notice standard that would trigger the statute of limitations at the earliest possible date—before an investor even knows, or could or should have known, that a violation exists.

Contrary to Petitioners' suggestion, there is no need for the Court to curtail the statute of limitations out of concern for "vexatious" securities litigation. Subsequent to the enactment of the PSLRA, fewer securities class actions are being filed than in the past.[5] Institutional investors are being appointed as lead plaintiffs, and previous concerns about lawyer-driven and meritless securities lawsuits have been addressed.

In fact, the standard advanced by Petitioners and their *amici* will promote exactly the types of premature and unnecessary lawsuits that Petitioners claim they seek to avoid and will create an envi-

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[5] Cornerstone Research, Securities Class Action Case Filings: 2009 Mid-year Assessment, 2 (2009), available at http://securities.cornerstone.com/pdfs/2009_mid-year_assessment.pdf (noting that securities class action filings in the first half of 2009 "dropped below the historical average.")

ronment that fosters distrust between investors and management. Petitioners propose a standard that would require investors to file lawsuits before they have any indication that anyone violated Section 10(b), resulting in lawsuits that otherwise never would have occurred. Moreover, the standard advanced by Petitioners would foster a climate of distrust between investors and corporate America, as according to Petitioners, shareholders must reject all "words of comfort" by management in addressing arguably bad news about a company. This is contrary to the avowed purpose of the federal securities laws, which were designed to foster an environment in which reasonable investors would, and should, trust management. If management's explanation is credible, then investor trust is reasonable.

To prevent premature and unnecessary litigation, foster investor trust in management and confidence in the integrity of capital markets, while still serving the purpose of the statute of limitations, the Court should affirm the Third Circuit's holding and find that mere misstatements without any indication that they were made with knowledge of their falsity are insufficient to constitute "storm warnings" and trigger the running of the statute of limitations within the meaning of Section 1658(b). Applying the Third Circuit's storm warnings standard to the facts in this case demonstrates that the Respondents' claims were timely, as they did not have, nor could they be charged with having, knowledge of the fraud more than two years before they brought their Section 10(b) claims.

ARGUMENT

I. THE THIRD CIRCUIT'S STORM WARNINGS STANDARD, WHICH REQUIRES SUFFICIENT INFORMATION OF CULPABLE ACTIVITY BEFORE THE STATUTE OF LIMITATIONS BEGINS TO RUN, COMPORTS WITH THE LANGUAGE OF SECTION 1658(b) AND WITH THE PURPOSES AND INTENT OF BOTH THE SARBANES-OXLEY ACT AND THE PSLRA

This case requires the Court to clarify when the statute of limitations for claims for violations of Section 10(b) and Rule 10b-5 commences. 15 U.S.C. 78j(b) ("Section 10(b)"); 17 C.F.R. 240 ("Rule 10b-5"). Section 1658(b) requires that such claims be brought within "2 years after the discovery of the facts constituting the violation; or . . . 5 years after such violation." 28 U.S.C. § 1658(b). The narrow question at bar concerns when a plaintiff has constructive knowledge or "inquiry notice" of facts supporting a Section 10(b) claim such that the Section 1658(b) limitations period begins to run.

The Third Circuit articulated a two-part test to determine when the two-year period begins to run based on inquiry notice. First, in accordance with the majority of other circuits, the Third Circuit explained that "[w]hether the plaintiffs, in the exercise of reasonable diligence, should have known of the basis of their claims depends on whether they had sufficient information of possible wrongdoing to place them on 'inquiry notice' or to excite 'storm warnings' of culpable activity." *See Merck*, 543 F.3d at 161, citing *Benak ex rel. Alliance Premier Growth Fund v. Alliance Capital Mgmt. L.P.*, 435

F.3d 396, 400 (3d Cir. 2006) (citations omitted).[6] Inquiry notice, in turn, occurs when a "reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning." *Id.*, citing *In re NAHC Sec. Litig.*, 306 F.3d 1314, 1325 (3d Cir. 2002) (internal quotations omitted). Second, "if the existence of storm warnings is adequately established the burden shifts to the plaintiffs to show that they exercised reasonable due diligence and yet were unable to discover their injuries." 543 F.3d at 161, citing *DeBenedictis v. Merrill Lynch & Co., Inc.*, 492 F.3d 209, 216 (3d Cir. 2007). In the instant case, the Third Circuit's analysis focused on the first part of the inquiry, *i.e.*, the sufficiency of information of possible wrongdoing necessary to trigger the statute of limitations.

The Third Circuit carefully considered that, in light of the heightened pleading requirements of the PSLRA, 15 U.S.C. § 78u-4(b), and its emphasis on discouraging premature and poorly pled allegations of securities fraud, the facts constituting inquiry notice "must be sufficiently probative of fraud—sufficiently advanced beyond the stage of a mere suspicion, sufficiently confirmed or substantiated" so

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[6] *See also GO Computer, Inc. v. Microsoft Corp.*, 508 F.3d 170, 179 (4th Cir. 2007); *Tello v. Dean Witter Reynolds, Inc.*, 494 F.3d 956, 970 (11th Cir. 2007); *Wolinetz v. Berkshire Life Ins. Co.*, 361 F.3d 44, 48 (1st Cir. 2004); *Ritchey v. Horner*, 244 F.3d 635, 639 (8th Cir. 2001); *Berry v. Valence Tech., Inc.*, 175 F.3d 699, 705 (9th Cir. 1999); *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1196 (10th Cir. 1998); *LaSalle v. Medco Research, Inc.*, 54 F.3d 443, 444 (7th Cir. 1995); *Jensen v. Snellings*, 841 F.2d 600, 607 (5th Cir. 1988). *But see Newman v. Warnaco Group, Inc.*, 335 F.3d 187, 193 (2d Cir. 2003) ("The [existence of] fraud must be probable, not merely possible.").

that a plaintiff can marshall those facts and "file a timely suit." *Merck*, 543 F.3d at 164, citing *Fujisawa Pharm. Co., Ltd. v. Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997). Thus, "in the context of a claim alleging falsely-held opinions or beliefs, investors must have sufficient information to suspect that the defendants engaged in culpable activity, *i.e.*, that they did not hold those opinions or beliefs in earnest" before they will be placed on inquiry notice. *Merck*, 543 at 166. Subsequent courts have interpreted this to mean that under the Third Circuit's standard, investors must possess information that the defendant acted with scienter before the statute of limitations begins to run. *See, e.g., Alaska Elec. Pension Fund v. Pharmacia Corp.*, 554 F.3d 342, 348 (3d Cir. 2009). As set forth below, the Third Circuit's holding that storm warnings do not exist until there is a sufficient indication that the defendant has engaged in culpable conduct should be affirmed, as it correctly advances the goals of eliminating premature and unnecessary litigation and allowing investors sufficient time to file their complaint, while also freeing defendants of stale claims.

A. The Third Circuit Correctly Held That, For Claims Of Securities Fraud, The Statute Of Limitations Does Not Begin To Run Until Plaintiffs Possess Some Reasonable Basis To Believe That Defendants Acted With Scienter, Which Is A Required Element Of A Securities Law Violation

The plain language of Section 1658(b) explicitly states that the two-year discovery period does not begin to run until a plaintiff "discover[s] . . . the

facts constituting the violation." 28 U.S.C. § 1658(b). A violation of Section 10(b) and Rule 10b-5 consists of the following elements: "(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security (4) reliance, often referred to in cases involving public securities markets (fraud-on-the-market cases) as 'transaction causation;' (5) economic loss; and (6) 'loss causation,' i.e., a causal connection between the material misrepresentation and the loss." *See Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341 (2005) (citations omitted). Thus, to state a claim for securities fraud under Section 10(b) and Rule 10b-5, it is undisputed that a complaint must, *inter alia*, "state with particularity facts giving rise to a strong inference" that a defendant acted with scienter (*i.e.*, knowingly or recklessly). *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007). "Scienter is not incidental to § 10(b), it is elemental." *Alaska*, 554 F.3d at 348.

The Third Circuit correctly held that there are no "storm warnings" of securities fraud unless and until there is a reasonable basis to suspect that a material misstatement was made with intent, *i.e.*, that there is "culpable activity." *See Merck*, 543 F.3d at 161; *Alaska*, 554 F.3d at 348. Contrary to Petitioners' assertion, there is no basis for an investor "to suspect the possibility that the defendant has engaged in securities fraud" (Pet. Br. at 21) absent some notice (actual or constructive) that the defendant acted with knowledge (or reckless disregard) that a statement is false. This proposition has been adopted by numerous courts,[7] while a contrary hold-

[7] *See, e.g., Alaska*, 554 F.3d at 348; *Sudo Prop., Inc. v. Terrebonne Parish Consol. Gov't*, 503 F.3d 371 (5th Cir. 2007).

ing (the Petitioners' position) would require a lawsuit to be initiated every time a company admitted to an incorrect statement, even if the mistake was wholly innocent.[8]

(plaintiff did not have inquiry notice of securities fraud where plaintiff had no information that defendant had deliberately misstated projections or that defendant was dishonest, disreputable, or otherwise acting inappropriately); *Law v. Medco Research*, 113 F.3d 781, 786 (7th Cir. 1997) (holding that inquiry notice is not triggered until plaintiffs knew or should have known that defendants "made a representation that was knowingly false"); *Betz v. Trainer Wortham & Co., Inc.*, 519 F.3d 863 (9th Cir. 2008) (plaintiff is not on inquiry notice until there exists suspicion of fraud); *In re Moody's Corp. Secs. Litig*, 599 F. Supp. 2d 493, 505 (S.D.N.Y. 2009) (articles claimed by defendants to be storm warnings did not mention fraud nor were sufficient to raise the probability of fraud); *In re DaimlerChrysler AG Sec. Litig.*, 269 F. Supp. 2d 508, 517 n. 5 (D. Del. 2003) (stating that "I am not persuaded that the statute of limitations starts to run before the plaintiffs have notice that the defendants acted with the requisite scienter in making the false misrepresentations in a Rule 10b-5 case."); *Swack v. Credit Suisse First Boston*, 383 F. Supp. 2d 223, 235 (D. Mass. 2004) ("Had [plaintiff] filed solely based upon the news articles and public information that Defendants claim put her on inquiry notice, her case would have been quickly dismissed . . . . Rather, she filed her complaint only after the Massachusetts investigation uncovered damaging e-mails that provide more specific evidence to support her claims."); *Carley Capital Group v. Deloitte & Touche, L.L.P.*, 27 F. Supp. 2d 1324, 1341 (N.D. Ga. 1998) ("Plaintiffs are not charged with inquiry notice until they knew or should have known that the Defendant acted with the requisite scienter."); *Great Neck Capital Appreciation Investment Partnership, L.P. v. PricewaterhouseCoopers, L.L.P.*, 137 F. Supp. 2d 1114, 1126 (E.D. Wis. 2001) (finding that company's issuance of press release announcing accounting irregularities did not trigger inquiry notice because press release "contained no facts suggesting that . . . the auditor acted with scienter").

[8] Similarly, there would be no reason to suspect a securities fraud violation absent some knowledge that the violation caused any damages. Nor is it good policy to require the filing of

Petitioners contend that the evidence supporting a particular element of a Section 10(b) claim is distinct from evidence supporting other elements, and that the Third Circuit improperly has required that a statute of limitations only begins to run when a plaintiff has information concerning each "discrete" category of information. *See* Pet. Br. at 22 (questioning "bright-line rule" of inquiry notice requiring a plaintiff to "possess[ ] discrete information specifically relating to scienter"); *id.* at 23 ("Under the court of appeals rule, a plaintiff would not be on inquiry notice until he possesses information specifically relating to all of the elements of the violation, including scienter"). Petitioners are wrong—the Third Circuit has not required information on each separate element of a 10b-5 claim before the limitations period has commenced. Under the Third Circuit's ruling, in order to trigger the limitations period, a plaintiff need only have knowledge that a false statement was made, along with an indication that other elements of the claim can be pled—including for instance, some reasonable basis to believe that the misstatement may have been made with knowledge of its falsity.

Petitioners also contend that the Third Circuit held that the limitations period does not begin to run until plaintiffs possess sufficient information to survive a motion to dismiss. Pet. Br. at 28-9. Again, the Third Circuit's inquiry notice standard contains no such requirement. Instead, the Third Circuit clearly explained that a plaintiff "need not know all of the details or 'narrow aspects' of the alleged

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securities fraud suits before the market reacts to a corrective disclosure reflecting the revelation of a fraud, s*ee Dura Pharm.*, 544 U.S. at 344, or before there is any evidence supporting other elements of a Section 10(b) claim, as such evidence may never be developed, so the filing would be unnecessary.

fraud to trigger the limitations period; instead, the period begins to run from 'the time at which plaintiff should have discovered the general fraudulent scheme.'" *Merck*, 543 F.3d at 163 (citing *In re NAHC*, 306 F.3d at 1326 (internal quotations omitted)); *see also Benak*, 435 F.3d at 400 ("Plaintiffs cannot avoid the time bar simply by claiming they lacked knowledge of the details or 'narrow aspects' of the alleged fraud. Rather, the clock starts when they 'should have discovered the general fraudulent scheme.'") (internal citation omitted). Furthermore, the Third Circuit deliberately restricted the quantum of information required to commence the limitations period by employing a "possibility standard," as opposed to a "probability standard," when evaluating "the likelihood of wrongdoing sufficient to constitute storm warnings." *Merck*, 543 F.3d at 164. Thus, while "a probability, in the sense of a nearly certain likelihood, of wrongdoing is not necessary to trigger storm warnings," the facts constituting inquiry notice, including scienter, must be "sufficiently advanced beyond the stage of a mere suspicion . . . to enable [a plaintiff] to tie up any loose ends and complete the investigation in time to file a timely suit." *Id.* at 164 (citing *Fujisawa*, 115 F.3d at 1335). The Third Circuit's inquiry notice standard therefore achieves the proper balance.

B. Congress Specifically Intended To Lengthen The Limitations Period In Actions Brought Under Section 10(B) And Rule 10b-5 So As To Allow Investors Adequate Time To Prepare Well-Pled Complaints Alleging Violations Of The Securities Laws

According to Petitioners, the "storm" commences for purposes of inquiry notice when the first cloud

appears on the horizon. Under Petitioners' standard, as soon as investors suspect any misstatement, whether innocent (without scienter), immaterial, or inconsequential (no damages), investors must race against the clock to determine whether a violation of the securities laws has actually occurred. Not only does this standard conflict with the statutory language in Section 1658(b) that the two-year limitations period commences upon "discovery" (rather than upon "suspicion of") *facts* constituting the violation, it would stand Congress's intent to avoid unsubstantiated lawsuits on its head. Indeed, under Petitioners' proposed rule, to guard against losing their claims, investors will no doubt file before there is evidence showing that a violation has occurred. By attempting to put plaintiffs on a "stop watch" at an earlier point in time based on a mere suspicion that the defendant made a misstatement, the extended limitations period established by the Sarbanes-Oxley Act would be rendered meaningless. *See* 148 Cong. Rec. S.7418 (July 26, 2002) ("[Section 1658(b)] [was] intended to lengthen any statute of limitations period under federal securities law, and to shorten none.").

Congress enacted the Corporate and Criminal Fraud Accountability Act, Pub. L. No. 107-204, 116 Stat. 800 ("Sarbanes-Oxley Act") following the revelation of several corporate accounting scandals in 2001 and 2002, which shook the financial markets and resulted in billions of dollars in investor losses as the share price of companies, such as Enron, Tyco and WorldCom, imploded amidst allegations of fraud. The Sarbanes-Oxley Act was intended to impose stricter accounting standards and tougher disclosure requirements on corporations in order to make them more accountable to shareholders. *See*

Pub. L. No. 107-204 (preamble) (stating that Sarbanes-Oxley was enacted "to protect investors by improving the accuracy and reliability of corporate disclosures made pursuant to the securities laws.")

As part of these sweeping reforms, Congress explicitly addressed the one-year/three-year statute of limitations periods applicable to Section 10(b) claims, which this Court transposed from Section 9(e) of the Exchange Act of 1934.[9] The fallout from *Enron* and other similar cases had made clear that these limitations periods unfairly restricted the ability of defrauded investors to recover, and in some instances, forced investors to forego claims altogether. *See* Senate Rep. No. 146, 107th Cong., 2d Sess. (2002) (noting that "innocent, defrauded investors attempting to recoup their losses face unfair time limitations under current law," and noting that "[i]n Washington state alone, the short statute of limitations may cost hard-working state employees, firefighters and police officers nearly $50 million in lost Enron investments, which they will never recover.").

Moreover, acknowledging Justices O'Connor's and Kennedy's admonition in *Lampf* that the "one and three" limitations period makes securities fraud actions "all but a dead letter for injured investors who by no conceivable standard of fairness or practicality can be expected to file suit within three

[9] *See Lampf, Pleva, Lipkind, Prupis A. Petigrew v. Gilbertson*, 501 U.S. 350, 364, n. 9 (1991). Notably, the only reform to private rights of action passed as part of the Sarbanes-Oxley Act was the extension of the limitations period. *See* 148 Cong. Rec. S1787 (Daily Ed. Mar. 12, 2002) (Statement of Sen. Leahy) (arguing "[i]t is time that the law be changed to give victims the time they need to prove their fraud cases.").

years after the violation occurred,"[10] Congress recognized that the complexities of securities fraud cases warranted a longer limitations period to allow investors sufficient time to investigate and adequately plead violations of the securities laws. *See* 148 Cong. Rec. S. 7420 (July 26, 2002) ("extending the statute of limitations is warranted because many securities frauds are inherently complex, and the law should not reward the perpetrator of a fraud, who successfully conceals its existence for more than three years . . . the short limitations period under current law is an invitation to take sophisticated steps to conceal the deceit.").

Significantly, Congress also noted that a one year statute of limitations running from the date the fraud is discovered is "particularly harsh on innocent defrauded investors":

> This short limitations period has the effect of placing true fraud victims on a "stop watch," from the moment they know that they have been cheated. As most prosecutors and victims will confirm, however, the best cons are designed so that even after victims are cheated, they will not know who cheated them, or how. Especially in securities fraud cases, the complexities of how the fraud was executed often take well over a year to unravel, even after the fraud is discovered. Even with use of the full resources of the FBI, a Special Task Force of Justice Department Attorneys, and the power of a federal grand jury, complex fraud cases such as Enron are difficult to unravel and rarely can be charged within a year.

[10] *See Lampf*, 501 U.S. at 378 (Kennedy, J., dissenting).

See S. Rep. No. 146, 107th Cong., 2d Sess. (2002); *see also* 148 Cong. Rec. S. 7420 (citing the Enron scandal as an impetus for extending the statute of limitations and explaining, "As recent experience shows, it only takes a few seconds to warm up the shredder, but unfortunately, it will take years for victims to put this complex case back together again."). The inquiry notice standard advocated by Petitioners starts the "stop watch" too early, is inconsistent with the language in Section 1658(b), and undermines the purpose of the extended limitations period established by Congress.

The idea that the statute of limitations begins to run as soon as an investor has a mere *suspicion* that a misstatement exists also conflicts with this Court's recent decision in *Tellabs*, 551 U.S. at 308, where this Court held that a complaint must "state with particularity facts giving rise to a strong inference" that a defendant acted with scienter (*i.e.*, knowingly or recklessly). It would be anomalous to elevate the standards for pleading scienter in a securities fraud case while at the same time requiring investors to suspect fraud in every error, and then bring those claims before they had, or should in the exercise of reasonable diligence have acquired, the "facts constituting the violation," *i.e.*, the kind of information needed to meet the *Tellabs* pleading standard.

C. Petitioners' Proposed Standard Undermines The Policies And Objectives Of The PSLRA

With the enactment of the PSLRA in 1995, Congress sought to address certain perceived "abusive practices" and reduce the number of purportedly "frivolous" lawsuits that survive motions to

dismiss.[11] To further these goals, the PSLRA imposed heightened pleading requirements for alleging false and misleading statements and scienter. *See*, *e.g.*, 15 U.S.C. § 78u-4(b)(1) (complaint alleging misleading statements or omissions must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed"); 15 U.S.C. § 78u-4(b)(2) (requiring plaintiffs to plead with particularity facts "giving rise to a strong inference that the defendant acted with the required state of mind"). Thus, in order to survive a motion to dismiss, plaintiffs must state with particularity "both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 308 (quotation omitted) (citing 15 U.S.C. § 78u-4(b)(l), (2)). Petitioners' proposed inquiry notice standard does not comport with the purposes and intent of the PSLRA or the recent amendment to Section 1658(b).

One of the main objectives of the PSLRA was to decrease the filing of premature and unnecessary securities lawsuits. *See Alaska*, 554 F.3d at 351 ("A rule that would place investors on inquiry notice of fraud the moment that the FDA questions the seemingly good faith scientific analysis of a pharmaceutical company would encourage putative plaintiffs to

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[11] *See* H.R. Rep. No. 104-369, at 41 (1995) (Conf. Rep.), reprinted in 1995 U.S.C.C.A.N. 730; *see also Newby v. Enron Corp.*, 338 F.3d 467, 471 (5th Cir. 2003) (discussing enactment of the PSLRA in response to an increase in securities fraud lawsuits perceived as frivolous).

file premature securities suits. In imposing heightened pleading requirements, Congress evinced an intent to discourage such suits."); *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 171 (2d Cir. 2005), ("[T]he level of particularity in pleading required by the PSLRA is such that inquiry notice can be established only where the triggering data 'relates directly to the misrepresentations and omissions' alleged."), *quoting Newman*, 335 F.3d at 193 (emphasis omitted). The correct standard of inquiry notice must not "require specific factual allegations . . . and then . . . punish the pleader for waiting until the appropriate factual information can be gathered by dismissing the complaint as time barred." *Levitt v. Bear Stearns & Co.*, 340 F.3d 94, 104 (2d Cir. 2003); *see also* S. Rep. No. 146, 107th Cong., 2d Sess. (2002) (noting "perverse incentive for victims to race into court," while "[p]laintiffs who wish to spend more time investigating . . . are punished under the [then-] current law."). Under Petitioners' standard, investors will be forced to file suit upon mere notice of a possible misrepresentation, even where such suits may never be ripe as information is never developed or discovered supporting key elements of the claim.[12]

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[12] Under Petitioners' standard, not only will investors be compelled to bring lawsuits before there is information sufficient to support the initiation of a claim, investors risk Rule 11 sanctions based on their failure to file an adequately pled complaint. *See, e.g., ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 579 F.3d 143 (2d Cir. 2009) (affirming sanctions against plaintiff's lawyers for bringing frivolous Section 10(b) action that failed to meet the requirements of Fed. R. Civ. P. Rule 9(b)). *See also* PSLRA, 15 U.S.C. § 78u-4(c)(3)(A)(ii) (sanction for frivolous Section 10(b) claim "is an award to the opposing party of the reasonable attorneys' fees and other expenses incurred in the action.").

Additionally, Petitioners' standard encourages defendants to manipulate their disclosures so as to trigger the statute of limitations, but then to use the PSLRA as a shield to prevent innocent, defrauded investors from bringing and maintaining meritorious lawsuits. *See* S. Rep. No. 146, 107th Cong. 2d Sess. (2002) ("In many securities fraud cases the short [one-year] limitations period under current law is an invitation to take sophisticated steps to conceal the deceit.") For example, a company may disclose that its prior statements were false, but not disclose (or wait two years to disclose) that insiders intended to misrepresent facts in the first place.

Finding that the statute of limitations commences when circumstances "place the potential plaintiff in possession of, or with ready access to, the essential facts he needs in order to be able to sue," *Fujisawa*, 115 F.3d at 1337, strikes the proper balance between the ability of class members to bring claims under the stringent pleading requirements of Fed. R. Civ. P. Rule 9(b) and the PSLRA, and the rights of defendants to have peace two years after claims against them have been, or should have been, discovered. *See Marks v. CDW Computer Ctrs., Inc.*, 122 F.3d 363, 368 (7th Cir. 1997) ("[I]nquiry notice does not begin to run unless and until the investor is able, with the exercise of reasonable diligence (whether or not actually exercised), to ascertain the information needed to file suit."), *cited with approval in NAHC*, 360 F.3d at 1325 n.4; *Benak* 435 F.3d at 401 ("Undergirding the inquiry notice analysis is the assumption that a plaintiff either was or should have been able, in the exercise of reasonable diligence, to file an adequately pled securities fraud complaint as of an earlier date."); *Lentell*, 396 F.3d at 168 ("So no claim should be filed unless and until it can be supported

by specific factual allegations" sufficient to meet the requirements of the PSLRA). Thus, Petitioners' arguments should be rejected.

D. Investors Should Not Be Deemed On Inquiry Notice Where Management Reassurances Through "Words Of Comfort" Allay Investor Concerns And Discourage Inquiry Into Potential Violations

It is undisputed that "[t]here are occasions when, despite the presence of some ominous indicators, investors may not be considered to have been placed on inquiry notice because the warning signs are accompanied by reliable words of comfort from management." *LC Capital Partners, LP v. Frontier Ins. Group, Inc.*, 318 F.3d 148, 155 (2d Cir. 2003). *See also DeBenedictis*, 492 F.3d at 218 (quoting *LC Capital*); *In re Alstom S.A.*, 406 F. Supp. 2d 402, 421 (S.D.N.Y. 2005) (same); *In re Pronetlink Sec. Litig.*, 403 F. Supp. 2d 330, 334-35 (S.D.N.Y. 2005) (rejecting defendants' argument that inquiry notice was triggered by defendants' downward revision of its subscriber numbers long before filing of complaint; "these disclosures were contravened by several allegedly false and misleading statements that could have caused a reasonable shareholder to think all was well;" for example, a defendant later stated at a shareholders' meeting that company had "very strong revenue-producing possibilities"). *Accord Sedona Corp. v. Ladenburg Thalmann & Co*, No. 03 Civ. 3120, 2005 WL 1902780, at *8 (S.D.N.Y. Aug. 9, 2005) (duty of inquiry not triggered when storm

warnings were tempered by defendant's specific denial of wrongdoing).[13]

Where the lulling statements, words of comfort or reassurances from management involve a scientific or technical issue, courts are especially ready to extend the date on which the statute of limitations begins to run. For example, in *Alaska*, 554 F.3d at 342, the Third Circuit held that investors were not put on inquiry notice of securities fraud based on a pharmaceutical company's materially false statements about a clinical study of Celebrex when an apparently legitimate scientific dispute arose between the FDA and Pharmacia. The Third Circuit reasoned that the thirteen months duration of the clinical study and a technical dispute between scientists about whether to use the full data or only a

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[13] *See also Siebert v. Nives*,, 871 F. Supp. 110 (D. Conn. 1994) (management's words of comfort were enough to dispel storm warnings caused by an ongoing FDIC investigation); *Lapin v. Goldman Sachs*, 506 F. Supp. 2d 221 (S.D.N.Y. 2006) (alarming newspaper reports and filing of an action for breach of fiduciary duty against brokers were insufficient to trigger commencement of limitations period where management reassurances "could persuade a reasonable investor into thinking that" storm warnings were innocuous); *Young v. Lepone*, 305 F.3d 1, 11 (1st Cir. 2002) (reversing statute of limitations-based dismissal and holding that auditor's letters to management did not amount to storm warnings and plaintiff was not on inquiry notice where auditor gave company a clean bill of financial health and made specific reassurances that certain reportable conditions "did not represent material weaknesses in the company's reporting systems"); *Newman*, 335 F.3d at 187 ("It was reasonable for plaintiffs not to inquire into [defendant's] statements because [defendant] had provided a seemingly benign explanation"); *In re Charles Schwab Corp. Sec. Lit.*, 257 F.R.D. 534 (N.D. Cal. 2009) (comfort words effective to dispel storm warning that investments were actually high risk despite a drop in net asset value and declining account balances).

portion of the data did not provide storm warnings of fraud to reasonable investors, and Pharmacia's reassuring statements operated as a sort of antidote to any storm warnings that may have existed. Similarly, in *Nathel v. Siegal*, 592 F. Supp. 2d 452 (S.D.N.Y. 2008), the defendants argued that certain conversations between themselves and plaintiffs put the plaintiffs on notice of the suspicious nature of the investments. The court rejected the defendants' arguments based on the technical nature of the fraud (involving tax rules applicable to oil and gas investments and the expertise of the defendants issuing the comfort words). *See also Seippel v. Sidley, Austin, Brown and Wood, LLP*, 399 F. Supp. 2d 283 (S.D.N.Y 2005) (IRS public guidance notices insufficient to put plaintiffs on inquiry notice because an assessment of accuracy of law firm's and financial services firm's comfort words "required more legal expertise than can be demanded of ordinary taxpayers.").

The inquiry notice standard advocated by Petitioners—effectively requiring investors to disbelieve or disregard all words of comfort from management—places an undue burden on investors and fosters distrust between companies and their investors that will be destructive to the financial markets. Contrary to Petitioners' contention, investors should not be required to suspect that every disclosure is fraudulent. *See Shapiro* v. *UJB Finan. Corp.*, 964 F.2d 272, 282 (3rd Cir. 1992) (construing *Virginia Bankshares*, 501 U.S. 1083, 1090-96 (1991)) (investors had no reason to doubt defendants' expressed beliefs, as it is well-settled that "a reasonable investor need not take a manager's statement of belief at anything less than face value."). Such a "guilty until proven innocent" standard is expensive, time consuming and

inefficient, and imposes on investors a heavy burden to inquire into every potential misstatement or else risk losing the ability to prosecute meritorious claims based on untimeliness.[14]

Petitioners' approach is also at odds with the presumption in open-market federal securities fraud actions that investors are entitled to rely on the market's investigation of a company's business and prospects as reflected in the company's stock price. *See Basic Inc. v. Levinson*, 485 U.S. 224, 244 (1988) ("With the presence of a market, the market is interposed between seller and buyer and, ideally, transmits information to the investor in the processed form of a market price. . . . The market is acting as the unpaid agent of the investor, informing him that given all the information available to it, the value of the stock is worth the market price.") (citation omitted). The standard advanced by Petitioners would foster a destructive environment in which investors could no longer rely on statements by management.

II. THE THIRD CIRCUIT CORRECTLY HELD THAT RESPONDENTS' CLAIMS WERE TIMELY

Petitioners cannot point to any fact suggesting that Respondents were aware, on or before November 6, 2001 (two years prior to November 6, 2003, when the first securities fraud complaint was filed), that Petitioners had fraudulently misrepresented their belief in the so-called "naproxen hypothesis."[15]

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[14] *See, e.g.*, Paul J. Zak & Stephen Knack, *Trust and Growth*, 111 Econ. J. 295, 298 (2001).

[15] The case involves claims that Merck misrepresented to investors information about increased risks of adverse cardiovascular events resulting from use of its blockbuster drug Vioxx.

Petitioners argue, and the District Court below held, that a September 21, 2001 FDA letter criticizing Merck's promotion of Vioxx provided inquiry notice of possible claims against Merck concerning Vioxx and effectively constituted rejection of the naproxen hypothesis. That letter does no such thing, as it did not specifically address any alleged false statements by Merck regarding its belief in the naproxen hypothesis. Rather, the FDA focused on Merck's promotional campaign for Vioxx—not on the scientific basis for the naproxen hypothesis or the increased risks of Vioxx. In the letter, the FDA stated that Merck's "promotional activities and materials" for the marketing of Vioxx were "false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations." 543 F.3d at 156-157. The letter explained:

> Although the exact reason for the increased rate of MIs observed in the Vioxx treatment group is unknown, your promotional campaign selectively presents the following hypothetical explanation for the observed increase in MIs. You assert that Vioxx does not increase the risk of MIs and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. ***That is a possible explanation***, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is

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Such risks potentially were evident from a clinical trial known as VIGOR, but Merck argued that the results were caused by the cardio-protective effects of the comparator drug used in the trial — naproxen. This latter claim is the "naproxen hypothesis."

> another reasonable explanation, that Vioxx may have pro-thrombotic properties.

Id. As the Third Circuit correctly decided, the FDA letter did not provide storm warnings of securities fraud to investors because it did not address any purported misrepresentations.[16] The FDA merely was enforcing regulations that provide that advertisements must not be "lacking in fair balance," 21 C.F.R. § 202.1(e)(6), and prohibit advertisements that " '[c]ontain[ ] a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience . . . or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.' " *Id.*

Second, as noted by the Third Circuit, "the FDA did not charge that the naproxen hypothesis was wrong or that Merck did not believe in the validity of its hypothesis; rather, the agency simply directed Merck to be more clear about the widely known

[16] *See Staehr v. Hartford Financial Services Group, Inc.*, 547 F.3d 406 (2d Cir. 2008) (reversing district court dismissal of complaint as barred by securities fraud statute of limitations because, *inter alia*, negative industry newsletters and state lawsuits against defendant relied on in defendant's motion to dismiss did not clearly demonstrate plaintiff should have discovered the fraudulent conduct); *Alaska*, 554 F.3d at 342 (inquiry notice, in securities fraud suits, ***requires storm warnings indicating that defendants acted with scienter***); *Sudo*, 503 F.3d at 371 (plaintiff did not have inquiry notice of securities fraud where plaintiff had no information that defendant had deliberately misstated projections or that defendant was dishonest, disreputable, or otherwise acting inappropriately); *Law*, 113 F.3d at 786 (inquiry notice not triggered until plaintiffs knew or should have known that defendants "made a representation that was knowingly false"); *Betz*, 519 F.3d at 863 (plaintiff is not on inquiry notice until there exists suspicion of fraud).

alternative hypothesis in its dealings with health care professionals and, presumably, consumers." *Merck* 543 F.3d at 170-71.

The FDA letter also could not be a storm warning because it had no effect on Merck's stock price, which dipped slightly following the disclosure of the FDA warning letter before closing higher than it did before that disclosure just a week and a half later. The Third Circuit held that "[a]lthough the lack of significant movement in Merck's stock price following the FDA letter is not conclusive, it supports a conclusion that the letter did not constitute a sufficient suggestion of securities fraud to trigger a storm warning of culpable activity under the securities laws." *Id.* (asserting that the "negligible impact" of an alleged storm warning on defendant's stock price bolstered conclusion that inquiry notice was not triggered).

Further dispelling any possibility that the FDA letter could constitute a storm warning were the repeated public reassurances by Merck that the company stood behind the naproxen hypothesis. For example, in an April 2002 conference call discussing Vioxx labeling changes, a Merck spokesperson reiterated the company's "belief that the effect seen in VIGOR were [sic] the results of the anti-platelet effect of naproxen. . . . So, I think that's a position Merck has always had and now its [sic] quite clearly laid out in the labeling."). *Merck*, 543 F.3d at 159 (Merck continued to reassure the investing public by use of the naproxen hypothesis).[17] At this time,

[17] The first lulling statement was issued on March 27, 2000, to the effect that in VIGOR, "significantly fewer thromboembolic events were observed in patients taking naproxen in the GI outcomes study, which "***is consistent with naproxen's ability to block platelet aggregation***." *Id.* at 168, 171 (emphasis added).

Respondents had no actual or constructive knowledge that there was a possibility that Vioxx significantly increased adverse cardiovascular events and was not commercially viable or that Merck did not believe the naproxen hypothesis. As the Third Circuit held, "reassurances can dissipate apparent storm warnings if an investor of ordinary intelligence would reasonably rely on them to allay the investor's concerns." *Merck*, 543 F.3d at 168 n.14.[18]

There was no reason to suspect that Merck did not believe the naproxen hypothesis until a study at Harvard in 2003 revealed an increased risk of heart attack in patients taking Vioxx compared with patients taking Celebrex and placebo. The study by the Harvard-affiliated Brigham and Women's Hospital found an increased risk of heart attack in patients taking Vioxx compared with patients taking a comparator drug and placebo. The Third Circuit correctly held that the Harvard study "for the first time belied Merck's repeated assurances that naproxen

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[18] *See also In re Ashanti Goldfields Sec. Litig.*, No. CV 00-0717 (DGT), 2004 WL 626810 (E.D.N.Y. Mar. 30, 2004) (denying defendant's motion to dismiss on statute of limitations grounds and holding that defendant's repeated statements of reassurance "allayed any concerns to the average investor"); *Lapin*, 506 F. Supp. 2d at 236 (where "investors were. . .being fed reassuring statements by Goldman" and where these announcements were "made both contemporaneously with and post-dating the news articles and the filing of the *Stefansky* complaint" and "reiterated the independence and objectively of Goldman's equity research . . . without qualification" the court found that "a reasonable investor's understanding of the extent of the alleged conflicts at Goldman during the Class Period did not, as a matter of law, give rise to a duty of inquiry"); *In re eSpeed, Inc. Sec. Litig.*, 457 F. Supp. 2d at 285 (S.D.N.Y. 2006) (duty to inquire not triggered where lulling statements were "reinforced" by defendants).

was responsible for the disparity in CV events in VIGOR and that Vioxx did not have a higher incidence of CVs compared to placebo . . . ." *Id.* at 172. Moreover, after the publication of the Harvard study, Merck's stock price dropped below the S & P 500 Index, and did not rise above that index during the remainder of the class period. *Id.*, at 159.

Prior to the publication of the Harvard Study and the Wall Street Journal article of October 30, 2003 entitled "VIOXX Study Sees Heart-Attack Risk," there was conflicting information regarding the cardiovascular safety profile of Vioxx. Moreover, whenever Merck did release safety data concerning Vioxx (such as the VIGOR study) Merck claimed that any adverse cardiovascular effect shown when Vioxx was compared to naproxen could be explained by "naproxen's ability to block platelet aggregation." *See id.* at 154. Thus, the VIGOR study did not establish that Petitioners committed fraud. It merely showed that Petitioners may have been wrong on the science, but provided no information to Respondents that they could use to allege that Petitioners had knowingly withheld pertinent information about Vioxx from the public. *See, e.g., Lentell*, 396 F.3d at 171 ("The articles cited by the district court described the conflicted situation of Wall Street's research analysts; but evidence of the outright falsity of Merrill Lynch's investment recommendations is stray and indiscriminate at best, and is insufficient to put plaintiffs on inquiry notice of the specific frauds alleged."); *Alaska*, 554 F.3d at 351 (inquiry notice of fraud not triggered by mere FDA questioning of the seemingly good faith scientific analysis of a pharmaceutical company).

As a result, the Third Circuit held, the statute of limitations did not begin to run until the Harvard study, only weeks prior to the filing of the first class-action securities complaint. *In re Merck*, 543 F.3d at 160. Accordingly, the Third Circuit's decision below is correct and should not be reversed.

Investors should not be required to file a securities fraud action as soon as management makes any statement that could *possibly* be false unless there are other facts that suggest that the misleading statement by company management was made with scienter. Nor should the mere questioning by third parties of statements by a company's management be sufficient to trigger the running of the limitations period for investors to bring a Section 10(b) claim. *See, e.g., Lentell*, 396 F.3d at 171; *In re Daimler-Chrysler*, 269 F. Supp. 2d at 511 (holding that 35 newspaper articles and press releases, "in which analysts and 'persons close to the negotiations' questioned whether the merger was really a merger of equals" failed to trigger limitations period for claims that defendants' statements that merger would be "merger of equals" were false) (citation omitted). *See also In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513, 527 (S.D.N.Y. 2005) (although public sources discussed the need to improve the company's inventory control processes and reduce inventory, "none of these events, although indicative of a potential inventory problem, were sufficient storm warnings to indicate to Plaintiffs the probability of a fraudulent failure to write down inventory in a timely fashion"); *Benak*, 435 F.3d at 402 ("[s]peculation should not be given the same weight as reports of objective wrongdoing."); *Berry*, 175 F.3d at 705 ("A press article's general skepticism about a company's future prospects is not sufficient

to excite inquiry into the specific possibility of fraud.").

CONCLUSION

As set forth above, consistent with Congress' policies to prevent premature and unnecessary litigation and foster an environment in which investors can place their trust in management, while also providing investors redress for securities fraud, this Court should find that investors are on inquiry notice of a possible Section 10(b) claim only when they have some indication that false statements were made with knowledge of their falsity. Accordingly, it is respectfully submitted that the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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AMICUS CURIAE BRIEF

No. 08-905

In The Supreme Court of the United States

MERCK & CO., INC., ET AL.,

Petitioners,

v.

RICHARD REYNOLDS, ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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INTEREST OF AMICUS CURIAE[1]

The Council of Institutional Investors is a not-for-profit association of more than 120 public, labor, and corporate pension funds with assets exceeding $3 trillion. Its members are major long-term shareholders with duties to protect the retirement assets of millions of American workers. The Council is an advocate for strong corporate-governance standards. Its members seek to protect fund assets through proxy votes, shareholder resolutions, negotiations with regulators, discussions with management, and, when necessary, litigation. The Council has previously appeared as an amicus in cases affecting shareholder rights. See, *e.g.*, *Stoneridge Investment Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U.S. 148 (2008); *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007); *Devlin* v. *Scardelletti*, 536 U.S. 1 (2002).

The interests of the Council and its members are directly implicated by this case. In the Private Securities Litigation Reform Act of 1995 (PSLRA), Congress recognized that institutional investors are uniquely positioned to represent the interests of absent class members and to prevent collusion between

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[1] Pursuant to Supreme Court Rule 37.6, counsel for amicus certifies that this brief was not authored in whole or in part by counsel for any party, and no person or entity other than amicus or its counsel has made a monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37.3(a), letters of consent from all parties to the filing of this brief have been filed with the Clerk.

defendants and plaintiffs' attorneys in settling lawsuits. See, *e.g.*, H.R. Conf. Rep. No. 104-369, p. 34 (1995) ("The Conference Committee believes that increasing the role of institutional investors in class actions will ultimately benefit shareholders and assist courts by improving the quality of representation in securities class actions."). Congress further recognized that institutional investors are America's largest shareholders and "have the most to gain from meritorious securities litigation." *Ibid.* (quoting testimony of Maryellen Andersen, then treasurer of the Council). Institutional investors also have the most to lose from meritless litigation that depletes shareholder wealth. See S. Rep. No. 104-98, p. 9 (1995) ("We are . . . hurt if a system allows someone to force us to spend huge sums of money in legal costs by merely paying ten dollars and filing a meritless cookie cutter complaint against a company or its accountants." (quoting testimony of Maryellen Andersen)). Accordingly, the Council has a strong interest in ensuring that the Court's interpretation of the PSLRA and the Sarbanes-Oxley Act of 2002 is based on an accurate picture of the current state of securities class-action litigation. The Council believes that the interpretation of these statutes should further Congress's manifest goal of allowing legitimate suits to proceed while discouraging meritless "strike suits."

SUMMARY OF THE ARGUMENT

This Court and Congress have repeatedly noted that private securities-fraud litigation can exact exorbitant costs on innocent corporations. Recognizing the high stakes involved, Congress enacted the PSLRA, heightening the pleading standards for section 10(b) actions. Congress heightened the pleading standards to curtail the rising number of meritless lawsuits while preserving investors' ability to recover on meritorious claims. The PSLRA appeared to accomplish the first of these goals, curbing meritless litigation. But as companies became more proficient at hiding fraudulent conduct, the second goal, preserving meritorious claims, began to suffer.

Then came Enron, WorldCom, Adelphia, and numerous other major business scandals that reflected massive audit failures and, in some cases, undetected accounting misconduct. The confidence of the investing public was justifiably shaken. Fears arose that the lack of trust in the markets would spell long-term problems for the markets and the economy.

Congress understood the need to act quickly to usher in fundamental reform and soon passed Sarbanes-Oxley. Recognizing the vital role that private securities litigation led by institutional investors plays in preventing corporate fraud, Congress extended the historical statute-of-limitations scheme, now requiring plaintiffs to file a section 10(b) action not later than the earliest of (1) two years after the discovery

of the facts constituting a violation or (2) five years after the violation.

The Council does not take a position on how the Court should interpret the Sarbanes-Oxley changes to the statute of limitations. The Council believes, however, that the strict test suggested by petitioners and their amici would have undesirable policy consequences. Under petitioners' suggested interpretation, the current statute of limitations would unreasonably preclude meritorious suits in contravention of Congress's express intent to ensure that plaintiffs have ample time to meet the PSLRA's stringent pleading standard. Further, petitioners' interpretation, if adopted, would effectively decrease the time available to investigate a potential fraud. This would force putative plaintiffs to bring suits based on knowledge of an innocent misstatement rather than the fraud the PSLRA intended to prevent. This test would thus increase meritless, lawyer-driven litigation—resulting in increased costs on the shareholders who will be forced to incur the expense of preemptive investigations into what may often be innocent misstatements. Finally, the attack on the value of private securities litigation by petitioners and some of their amici is unwarranted. Private enforcement of the securities laws is an essential supplement to federal enforcement activity and has accordingly strengthened, not weakened, the United States' capital markets.

ARGUMENT

When construing the laws governing securities-fraud claims, this Court has sought to "prescribe a workable construction" that honors the legislature's "twin goals: to curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims." *Tellabs, Inc.*, 551 U.S., at 322. Petitioners' proposed standard would contravene both of these goals because it would preclude meritorious suits based on an inability to timely ascertain the fraud committed and would increase preemptive filings based on innocent misstatements.

The Council believes that the Court should interpret §1658(b) to preserve Congress's intended balance between discouraging frivolous, lawyer-driven litigation and enabling investors to recover on meritorious claims. The PSLRA and Sarbanes-Oxley have achieved those twin goals by dramatically increasing the proportion of pretrial dismissals and increasing the number of institutional investors as lead plaintiffs in securities class actions.

I. CONGRESS RECOGNIZED THAT SECURITIES LITIGATION UNDER THE PSLRA REQUIRES AMPLE TIME TO INVESTIGATE AND PREPARE.

A. Identifying Fraud Takes Time.

1. Investors Face Significant Challenges in Acquiring and Analyzing Information.

Stock ownership has become a preferred investment of the general public, especially for people saving for retirement. An estimated "fifty-five percent of American families now own stock in public companies." Biggs, Shareholder Democracy: The Roots of Activism and the Selection of Directors, 39 Loy. U. Chi. L.J. 493, 498 (2008). This amounts to more than 90 million Americans owning shares of stock through individual investments or mutual funds. NYSE, A Guide to the NYSE Marketplace, at 2 (2006), http://www.nyse.com/pdfs/nyse_bluebook.pdf. And investors have numerous investment options from which to choose.

More than 2,600 companies are listed on the New York Stock Exchange, representing a total global market capitalization of over $22.6 trillion. *Id.*, at 3. In 2006, almost 1.8 billion shares, valued at over $68.5 billion were traded on the NYSE on an average trading day. *Ibid.* The NASDAQ lists approximately 3,100 companies and, on average, trades more shares per day than any other market in the United States. See NASDAQ, Get the Facts, http://www.nasdaq.com/reference/market_facts.stm (last visited Oct. 21, 2009).

With the large number of securities available and many investors holding a diversified portfolio of stocks, monitoring investments for fraud is no easy task. In *Dura Pharmaceuticals, Inc.* v. *Broudo*, this Court held that plaintiffs in securities-fraud cases must allege and ultimately prove a causal relationship between a stock-price decline and the public revelation of the fraud. 544 U.S. 336, 345-346 (2005). Because stock prices are assumed to reflect the sum of all publicly available information concerning the company and the industry in which it operates, potential plaintiffs must be keenly aware of new information released into the public sphere. And the amount of new information released is voluminous.

Companies introduce numerous types of information into the marketplace on a daily basis. Each company alone may make more than ten filings per year with the SEC, not counting restatements. Additionally, companies regularly file press releases, maintain websites containing company information, news, and events, and, in the case of pharmaceutical companies, conduct studies regarding their existing products, as well as those still in development, and release reports of the results.

Restatements, for example, are a type of material information particularly likely to move the market. A restatement is "the process of revising previously issued financial statements to reflect the correction of an error in those financial statements." Fin. Accounting

Series, Statement of Fin. Accounting Standards No. 154—Accounting Changes & Error Corrections, at 3 (May 2005), http://www.fasb.org/cs/BlobServer?blobcol=urldata&blobtable=MungoBlobs&blobkey=id&blobwhere=1175818827484&blobheader=application%2F.pdf. A restatement need not be made if an item is not material. See *id.*, at 11 ("The provisions of this Statement need not be applied to immaterial items.").

The number of financial restatements has been increasing significantly over recent years, hitting an all time record in 2006 with as many as 1,538 restatements involving nearly 10% of all public companies. Grothe, The Errors of Their Ways, at 1 (Feb. 27, 2007), http://www.pbs.org/nbr/pdf/GlassLewis-Errors.pdf (hereinafter Error of Their Ways). In 2006, 146 companies restated more than once, with 25 companies restating multiple times in the same year. *Ibid.* Although the number of restatements declined to 1,272 in 2007, Townsend & Baldwin, Revenue Recognition for Collaborative Arrangements in the Biotechnology Industry, at 9 (Aug. 8, 2008), http://www.bio.org/tax/funding/revenuerecognitionprinciplesstudy.pdf, "the number is still quite high." SEC Advisory Committee, Final Report of the Advisory Committee on Improvements to Financial Reporting to the United States Securities and Exchange Commission, at 76 (Aug. 1, 2008), http://www.sec.gov/about/offices/oca/acifr/acifr-finalreport.pdf (hereinafter SEC Advisory Committee Report).

In addition to restatements, companies must disclose if they have material weaknesses. Material

weaknesses are control deficiencies that result in more than a remote likelihood that material misstatements in annual or quarterly financial reports will not be prevented or detected. Grothe, The Materially Weak, at 5 (Feb. 27, 2007), http://www.pbs.org/nbr/pdf/GlassLewis-Materially.pdf (hereinafter Materially Weak). Between 2004 and 2006, a total of 2,400 companies, approximately 17% of all U.S.-listed companies, disclosed at least one material weakness. *Id.*, at 7. In that same period, companies disclosed a total of 6,718 material weaknesses. *Id.*, at 11.

Investors have the monumental task of sorting through the mass of information available in the public sphere to determine whether a company has engaged in securities fraud. And investors lack a specific type of disclosure that would clearly indicate that a fraud has occurred. Even restatements and disclosures of material weaknesses cannot be trusted as per se indicators of fraud. Innocent misstatements are very common in large, complex companies with numerous subsidiaries.

Additionally, because a significant portion of restatements involve minor or non-core corrections, the impact of a restatement—and its use as a proxy for fraud—is questionable. For example, restatements from non-core expenses (*i.e.*, non-operating or non-recurring expenses) increased from approximately 20% of total restatements in 1997 to nearly 40% in 2006. Scholz, The Changing Nature and Consequences of Public Company Financial Restatements 1997-2006, at 5 (April 2008), http://www.treas.gov/press/

releases/reports/FinancialRestatements_1997_2006.pdf (hereinafter The Changing Nature). In fact, nearly half of all restatements in 2006 involved accounting for non-operating expenses, non-recurring events, and reclassifications that typically do not have discernibly negative market reactions. *Id.*, at 1.

A potential plaintiff's task of sorting through innocent information from what is fraudulent is further complicated by the standard operating procedures of companies making restatements. Once a company notifies the SEC and investors that a restatement may be necessary because a material error has been identified, "companies often go into a 'dark period' and issue very little financial information to the public." SEC Advisory Committee Report, at 6. The "dark period" inhibits a potential plaintiff from uncovering whether the company has committed securities fraud or has simply made a benign misstatement. "This silence creates significant uncertainty regarding the size and nature of the effects on the company of the error or the issues leading to the restatement." *Id.*, at 85. In fact, the SEC Advisory Committee opined that "the current disclosure surrounding a restatement is often not adequate to allow investors to evaluate the company's operations." *Ibid.*

The "dark period" is often used as a shield against potential litigation. See *ibid.* ("We understand that, in the current legal environment, companies are often unwilling to provide disclosure of uncertain information."). But without the information necessary

to determine whether a company has committed fraud or simply made a benign misstatement, potential plaintiffs are hard pressed to meet the higher pleading standard of the PSLRA.

2. Petitioners' Standard Would Increase the Difficulties Investors Face in Identifying Fraud.

Recognizing the hardship of ferreting out fraud and in response to several massive frauds that shook the financial markets, Congress passed Sarbanes-Oxley. In extending the limitations period for section 10(b) claims to two years from the date the parties know of the fraud and five years from when the fraud actually occurred, Congress acted out of concern that the preexisting one and three-year periods would foreclose harmed investors that were unable to timely prepare complaints sufficient to satisfy the PSLRA's heightened pleading requirements. Congress did not intend for §1658(b) to bar injured shareholders from filing a meritorious securities-fraud lawsuit based on the statute of limitations. "Statutes of limitations are simply not proper means of deciding legitimate cases which should be decided on the merits—that is the role of the underlying substantive law." S. Rep. No. 107-146, p. 9 (2002). Instead, Congress extended the statute of limitations because "[e]specially in complex securities fraud cases, the current short statute of limitations may insulate the worst offenders from accountability and rewards those who can successfully

cover up their misconduct for at least a year." S. Rep. No. 107-146, p. 8.

Congress had ample reason to be wary of a short statute of limitations. "In many securities fraud cases the short limitations period under current law is an invitation to take sophisticated steps to conceal the deceit. The experts have long agreed on that point, and unfortunately they have been proven right." *Id.*, at 9. Public companies have already begun engaging in these deceptive tactics.

For example, there is an upward trend in "stealth restatements." Errors of Their Ways, at 1. In a "stealth restatement" a company does not file amended financial statements and does not make the Form 8-K filings with the SEC to warn investors that their past reports were not reliable. *Ibid.* Instead, the company merely corrects its financials in its next regularly scheduled annual and quarterly filings. *Id.*, at 20. In 2006 alone, approximately 40% of companies filed their restatements without using amended filings. *Ibid.* At the same time, the incidence of restatements involving fraud as identified by an SEC issued Accounting and Auditing Enforcement Release or by company admission has decreased from 29% of all restatements in 1997 to 2% in 2006, The Changing Nature, at 12-13—evidence that companies have become better at hiding the frauds they perpetrate.

Additionally, companies are often deficient in providing full disclosure, even when statutorily required. For instance, although a restatement strongly

suggests that a material error in a company's financial statements was not detected, "[c]uriously, the companies that restated [in 2006] aren't necessarily the same ones that disclosed material weaknesses." Errors of Their Ways, at 16. This result may not be surprising when one considers that about 95% of all companies that disclosed material weaknesses immediately after Sarbanes-Oxley took effect "had told investors that their controls were effective, right up through the last quarter before their auditors conducted their own independent internal-control evaluations." Materially Weak, at 20. "That tells us that management either lied or just wasn't aware of the weaknesses, neither of which bode well for investors." *Ibid.*

Under petitioners' proposed standard, companies committing fraud would have further incentives to "hide the ball"—releasing information that appears to be a benign misstatement, knowing that they will have a strong legal argument that such information would start the statute of limitations and potentially curtail any meritorious litigation. See S. Rep. No. 107-146, p. 8. Petitioners' proposed standard would thus allow a company to manipulate the publicly available information in a way that serves as both a sword and a shield.

B. Institutional Investors Do Not Race to the Courthouse.

Congress knew the significant investment of time and resources needed to meet the PSLRA's high pleading standard once potentially fraudulent conduct is known by the investor. In deciding to change the one-year limitations period to two years, the Senate Judiciary Committee explained that "[t]he one year statute of limitations from the date the fraud is discovered is . . . particularly harsh on innocent defrauded investors," because "the best cons are designed so that even after victims are cheated, they will not know who cheated them, or how." S. Rep. No. 107-146, p. 9. The committee further explained that "[e]specially in securities fraud cases, the complexities of how the fraud was executed often take well over a year to unravel, even after the fraud is discovered." *Ibid.*

In addition to the burden of meeting the requisite pleading standards, institutional investors must also determine if litigation is warranted based on the merits of the case and their fiduciary duties. Therefore, once evidence of a potential fraud is discovered, institutional investors conduct a careful evaluation to weigh the benefits and burdens of protracted litigation, decreasing the time available under the statute of limitations.

For example, before an action can be filed, the State of Wisconsin Investment Board (SWIB) requires its internal legal staff to extensively evaluate the case

and make a recommendation to a committee consisting of the chief legal counsel, the executive director, and the chief investment officer. See SWIB, Sec. Lit. Class Action Procedures, http://www.swib.state.wi.us/Litigation.aspx (last visited Oct. 10, 2009). If the committee members unanimously agree, the chief legal counsel may then retain outside counsel to independently evaluate the merits of the case. *Ibid.* Only after the committee unanimously approves the outside counsel's recommended action may SWIB initiate, join, appear in, or submit a filing in any public-market corporate-fraud litigation. *Ibid.*

The Iowa Public Employees' Retirement System (IPERS) conducts a similar process to determine whether to serve as a lead plaintiff in a securities-fraud case. The IPERS internal evaluation requires its legal staff to determine, among other things, whether there is a "very strong" factual and legal basis indicating that it is "highly probable" that litigation would be successful, the "potential prospective positive impact that corporate governance changes required as a result of legal action may have on the value of IPERS' current holdings," and "[w]hether there are staffing or resource constraints that might make it difficult to effectively pursue the case actively." Iowa Pub. Employees' Ret. Sys., Sec. Monitoring & Lit. Policy, at 2-3 (Sept. 2008), http://www.ipers.org/publications/misc/pdf/financial/investments/policies/secmonlit.pdf. The results of the comprehensive internal evaluation are presented to the board of directors for review and determination. *Id.*, at 3. The Board

may also consult with outside organizations to aid in its decision. *Id.*, at 4.

As shown by the detailed process undertaken by the SWIB and IPERS, securities litigation is not entered into lightly by institutional investors. See Cal. State Teachers' Ret. Sys. Corporate Governance Program Policies, at 3-5 (Apr. 2006), http://www.calstrs.com/Investments/CorpGovPolicies_200604.pdf (requiring the board of directors to determine whether to seek lead plaintiff status based on an internal evaluation and an independent assessment from outside counsel). Despite the comparably larger holdings of a stock than an individual investor, institutional investors simply do not have the resources to investigate every suspicious communication released by a company for fraudulent activity. Instead, based on the considerable resources required to conduct an internal evaluation, institutional investors must be judicious in investigating a potential fraud.

Congress extended the statute-of-limitations scheme to provide potential plaintiffs with sufficient time to fully investigate a possible securities-fraud claim rather than have plaintiffs race to the courthouse and rely on artful pleading. Institutional investors are precisely the type of potential plaintiffs that will use this time wisely, conducting a full investigation before bringing an action.

C. Petitioners' Standard Will Increase Meritless Filings.

Because extensive investigation is often required to uncover a fraud, under petitioners' standard, plaintiffs will be faced with a Hobson's choice—either investigate every potential misstatement for fraudulent intent (an untenable option for even the most well-resourced institutional investors), or preemptively file lawsuits to preserve their rights. Similar to the one-year statute of limitations formerly present for 10(b) actions, petitioners' proposed standard "sets up a perverse incentive for victims to race into court, so as not to be barred by time, and immediately sue." S. Rep. No. 107-146, p. 9. Indeed, "[p]laintiffs who wish to spend more time investigating the matter or trying to resolve the matter without litigation" will be punished under petitioners' standard. *Ibid.* And those that sit back without investigating the misstatement as a hedge against a decrease in stock price do so at their own peril—running the risk that a court of competent jurisdiction will conclude that the plaintiffs could and should have discovered the fraudulent activity and are thus barred from bringing suit.

Shortening the effective statute of limitations "does nothing to discourage frivolous cases, as a plaintiff operating in bad faith would have little trouble meeting the [two] year deadline and simply throwing in every possible defendant and every claim." *Ibid.* "Instead of stopping bad faith suits, the short statute [would] merely block[ ] the meritorious claims of fraud victims." *Ibid.* Petitioners' proposed

standard would require investors to question every potential misstatement and preemptively file suits based not on concrete investigation findings but instead on artful pleading.

II. Private Enforcement Actions Are Crucial to Deterring Fraud.

A. Private Securities Litigation Is an Essential Supplement to Public Enforcement.

When Congress enacted the PSLRA, it recognized that private securities litigation is "an indispensable tool with which defrauded investors can recover their losses" and is crucial "to the integrity of American capital markets." H.R. Conf. Rep. No. 104-369, p. 31. Similarly, the Court has emphasized that "implied private actions provide 'a most effective weapon in the enforcement' of the securities laws and are 'a necessary supplement to [SEC] action.'" *Bateman Eichler, Hill Richards, Inc.* v. *Berner*, 472 U.S. 299, 310 (1985) (quoting *J.I. Case Co.* v. *Borak*, 377 U.S. 426, 432 (1964)).

The SEC has also consistently stressed the importance of private litigation as a supplement to its limited enforcement resources. Private enforcement is particularly important because funding for public enforcement has not kept pace with growth in the securities market. See Securities Litigation Uniform Standards Act of 1997, Hearing on S. 1260 Before the

Subcomm. on Sec. of the S. Comm. on Banking, Housing, and Urban Affairs, 105th Cong. (1997) (prepared testimony of Arthur Levitt, SEC Chairman, and Isaac C. Hunt, SEC Commissioner), http://www.sec.gov/news/testimony/testarchive/1997/tsty1997.txt ("Private actions are an especially important supplement to the Commission's enforcement program today because of the phenomenal growth of the securities industry during a time when the Commission's staff and budget levels have remained relatively constant."); see also Seligman, The Transformation of Wall Street: A History of the SEC and Modern Corporate Finance 630 (3d ed. 2003) (during most of the 1990s, the SEC's budget grew at 6% per year, while virtually every significant measure of securities activity grew far faster).

Some of the amici supporting petitioners suggest that private securities litigation has caused the flight of capital from the United States. But this is a dubious proposition. A recent Goldman Sachs study concluded that economic and geographic factors, rather than the legal environment, were primarily responsible for the shift in global capital-markets activity. See O'Neill et al., Is Wall Street Doomed?, at 1 (Feb. 14, 2007), http://www.law.duke.edu/globalmark/web/conferences/2007roundtable/pdf/goldmansachs.pdf (explaining that the United States has been losing market share for decades and that growth of capital markets outside the United States is a "natural consequence of economic growth and market maturation elsewhere").

Similarly, an Ernst & Young report concluded that the relative increase in non-U.S. listings of non-U.S. companies is due primarily to more liquid overseas markets and a longstanding trend for companies to go public in their home countries rather than in response to regulations in the United States. See Ernst & Young, Global Capital Market Trends—U.S. IPO Market Strength and Leadership 2006 Year in Review & 2007 Outlook, at 4 (Aug. 2007), http://www.cfo.com/whitepapers/index.cfm/download/10317011. Ernst & Young also found that the United States is very successful in attracting those companies that choose not to list locally and put themselves "in play" among capital market competitors. See *id.*, at 4-5. That success is especially impressive because commissions and fees to take a company public are higher in the United States than in other countries. See Chen & Ritter, The Seven Percent Solution, 55 J. Fin. 1105, 1112-1113 (2000). Other analysts have questioned the quality of foreign IPOs. See Henry, London's Freewheeling Exchange, BusinessWeek, Nov. 27, 2006, at 40 (describing evidence that London's lax standards attract companies that could not go public in the U.S.); *ibid.* (noting that, according to a Dealogic study, IPOs greater than $100 million were up 20% on the New York Stock Exchange in 2006, compared to only 11% on the London Stock Exchange).

Further, foreign firms that have cross-listed on American exchanges have lower costs of capital and increased valuations, demonstrating that investors

rate companies more highly when they subject themselves to United States laws and regulations. See, *e.g.*, NYSE Group, Inc., Foreign Firms Cross-Listed in U.S. Valued Higher, The Exchange, Vol. 12, No. 10 (Oct. 2005), http://www.nyse.com/about/publication/1127731093408.html; Niemeier, American Competitiveness in International Capital Markets (Sept. 30, 2006), http://www.pcaobus.org/News_and_Events/Events/2006/Speech/09-30_Niemeier.aspx (concluding that "claims that the cost of securities regulation in the United States . . . has damaged the competitiveness of U.S. companies and markets are to my mind overstated"); *ibid.* ("the U.S. financial reporting and disclosure system has strengthened U.S. markets' resilience for the long-term and contributes significantly to the competitive edge the companies that list in U.S. markets enjoy").

In short, private enforcement of securities laws is not responsible for increased competition from foreign capital markets. Rather, as Congress and the SEC have long recognized, such enforcement is crucial to preserving the integrity and thus the preeminence of the United States' markets.

B. The PSLRA and Sarbanes-Oxley Have Succeeded in Reducing Meritless Litigation and Agency Costs.

1. The PSLRA and Sarbanes-Oxley Have Reduced Meritless Litigation.

In enacting the PSLRA, Congress aimed to reduce the settlement value of meritless lawsuits by permitting dismissal before costly discovery. See H.R. Conf. Rep. No. 104-369, p. 37; S. Rep. No. 104-98, p. 14. Combined with Sarbanes-Oxley, the PSLRA has served that purpose. The pretrial dismissal rate for securities class actions has nearly doubled since enactment of the PSLRA. Between 1991 and 1995, dismissals accounted for approximately 19% of dispositions. Foster, Miller, & Plancich, Recent Trends in Shareholder Class Action Litigation: Filings Plummet, Settlements Soar, at 4 (Jan. 2007), http://www.nera.com/image/BRO_Recent_Trends_SEC1288_FINAL_0307.pdf. However, between 2004 and 2006, over 41% of all cases filed have been dismissed. See Plancich & Starykh, Recent Trends in Securities Class Action Litigation: 2009 Mid-Year Update, at 16 (July 2009) (hereinafter 2009 Mid-Year Update).

> "The high and apparently rising dismissal rate is not consistent with the thesis that baseless suits mature into extortionate settlements. Instead, the declining rates of filings support the view that doctrinal and legislative developments reviewed above are having a most sobering impact on decisions

> to prosecute securities class action settlements." Investor Protection: A Review of Plaintiffs' Attorney Abuses in Securities Litigation and Legislative Remedies, Hearing Before the Subcomm. on Capital Markets, Ins., & Gov. Sponsored Enters. of the H. Comm. on Fin. Servs., 109th Cong. 66 (2006) (prepared statement of James D. Cox), http://financialservices.house.gov/media/pdf/109-102.pdf.

Further, while there is no consistent post-PSLRA trend in the total number of securities class actions filed, the number of class-action filings dropped significantly in the first half of 2009. The 87 filings in the first half of 2009 was more than 22% less than the total filings in each individual half of 2008. Cornerstone Research, Securities Class Action Filings—2009 Mid-Year Assessment, at 2 (2009), http://securities.stanford.edu/clearinghouse_research/2009_YIR/Cornerstone_Research_Filings_2009_MidYear_Assessment.pdf (hereinafter 2009 Mid-Year Assessment). If this filing rate continues, the total for 2009 would represent an approximate 12% decrease from the annual average for the twelve years ending December 2008. *Id.*, at 4.

In contrast, the occasional spikes in filings in the post-PSLRA period do not reflect any general trend. For example, plaintiffs filed a large number of actions in 2007 and 2008 due to the subprime lending collapse. "As the subprime lending meltdown grew into a full-blown credit crisis, the number of filings related to the credit crisis also grew, both in absolute number

and as a fraction of all filings." 2009 Mid-Year Update, at 1. But "[t]he recent decline in market volatility raises the possibility of a return to the subdued levels of filing activity observed from the third quarter of 2005 to the second quarter of 2007." 2009 Mid-Year Assessment, at 5. In fact, only 2.8% of companies in the S&P 500 index were named defendants in a federal securities class action in the first half of 2009 compared with 9.2% in 2008. *Id.*, at 8.

Additionally, since Congress enacted the PSLRA and Sarbanes-Oxley, the average and median settlement amounts have increased—reflecting a higher proportion of meritorious litigation. After the passage of Sarbanes-Oxley, the average settlement has been nearly $50 million compared to an average of $17 million in the pre-Sarbanes-Oxley period. 2009 Mid-Year Update, at 22; see also Ryan & Simmons, Securities Class Action Settlements—2008 Review and Analysis, at 2 (2009), http://www.cornerstone.com/files/Publication/0e3f5375-16a5-4a03-90a0-0174fd516581/Presentation/PublicationAttachment/c3336b87-6ac3-44e7-8ab1-018ba7015c48/Cornerstone_Research_Settlements_2008_Analysis.pdf ("The median amount for cases settled in 2008 was $8 million . . . represent[ing] an increase over the median for all the cases settled from 1996 through 2007."); Larsen & Buckberg, SEC Settlement Trends: 2Q09 Update, at 2 (Aug. 3, 2009), http://www.nera.com/image/PUB_Settlements_Update_0809.pdf ("[T]he average [SEC settlement] through the first half of 2009 was $10.1

million, an increase over the full-year average of $8.4 million in 2008.").

The higher settlement values exhibit "more precise targeting of securities class actions against firms likely to have committed fraud." Johnson, Nelson, & Pritchard, Do The Merits Matter More? The Impact of the Private Securities Litigation Reform Act, 23 J.L. Econ. & Org. 627, 649 (2007); see also *id.*, at 646-647 (concluding that post-PSLRA litigation is more closely correlated to restatements and abnormal insider stock sales, and less likely to be triggered by voluntary earnings warnings). The PSLRA has also resulted in fewer quick settlements, further indicating a shift away from meritless suits that defendants settle speedily and for small amounts to avoid the expense of defense. See Choi, The Evidence on Securities Class Actions, 57 Vand. L. Rev. 1465, 1496-1498 (2004).

Rather than increasing meritless lawsuits, the PSLRA may have reduced the number of meritorious class actions. One study found that a significant number of non-nuisance suits lacking pre-filing hard evidence, as well as non-nuisance suits involving smaller frauds, would not be brought after the PSLRA. See Choi, Do the Merits Matter Less After the Private Securities Litigation Reform Act?, 23 J.L. Econ. & Org. 598, 598 (2007). Others have similarly cautioned that the PSLRA may screen out meritorious claims. See, *e.g.*, Stout, Type I Error, Type II Error, and the Private Securities Litigation Reform Act, 38 Ariz. L. Rev. 711, 711 (1996) (PSLRA is

insufficiently attentive to the economic costs of "false negatives," or elimination of legitimate fraud claims, as opposed to "false positives"); Talley & Johnsen, Corporate Governance, Executive Compensation, and Securities Litigation, Univ. of S. Cal. Law Sch., Olin Research Paper No. 04-07, at 25 (2004), http://ssrn.com/abstract=536963 (PSLRA has discouraged meritorious litigation in addition to frivolous litigation).

In sum, the empirical evidence does not indicate that accepting petitioners' proposed standard is necessary to further the PSLRA's goal of reducing meritless filings. In fact, the evidence suggests that adopting the strictest possible standard may increase the number of preemptive lawsuits, see S. Rep. No. 107-146, p. 9, and tilt the balance struck by the PSLRA and Sarbanes-Oxley too far in the direction of eliminating meritorious suits. Cf. The Common Sense Legal Reforms Act of 1995, Hearing on H.R. 10 Before the Subcomm. on Telecomms. & Fin. of the H. Commerce Comm., 104th Cong. 1 (1995) (prepared testimony of Arthur Levitt, SEC Chairman), http://www.sec.gov/news/testimony/testarchive/1995/spch025.txt ("Although we might strive for a system in which corporate issuers never spend a dime defending meritless claims, we should recognize that it is impossible to eliminate all meritless cases without also affecting the cases that do have merit and thereby eroding the deterrence provided by private actions.").

2. The PSLRA and Sarbanes-Oxley Have Reduced Agency Costs.

Endorsement of petitioners' proposed standard is also unnecessary to accomplish another principal goal of the PSLRA: the reduction of agency costs resulting from the divergence of interests between plaintiffs, who might hold only a nominal number of shares in the defendant company, and their lawyers. Congress enacted the PSLRA in large part to address "the manipulation by class action lawyers of the clients whom they purportedly represent." H.R. Conf. Rep. No. 104-369, p. 31. Congress was concerned about lawyers inducing "professional plaintiffs" to file suits that extract attorneys' fees at the expense of investors, who either receive inadequate compensation for wrongdoing or bear the costs of settling a meritless case. See *id.*, at 32-33; S. Rep. No. 104-98, p. 6.

Congress aimed to stop such "lawyer-driven lawsuits" by "giving control of the litigation to lead plaintiffs with substantial holdings." H.R. Conf. Rep. No. 104-369, p. 32. Accordingly, the PSLRA's procedures for the appointment of lead plaintiffs and lead counsel sought to "increase the likelihood that institutional investors will serve as lead plaintiffs." *Id.*, at 34; see also S. Rep. No. 104-98, p. 11 ("The Committee believes that an institutional investor acting as a lead plaintiff can, consistent with its fiduciary obligations, balance the interests of the class with the long-term interests of the company and its public investors."). The PSLRA and Sarbanes-Oxley have achieved that aim.

The percentage of securities class actions with an institutional lead plaintiff has grown significantly since the PSLRA's enactment, and particularly since Sarbanes-Oxley became law. In 1996, unions and pension funds were lead plaintiffs in less than 3% of cases filed. See PricewaterhouseCoopers, 2003 Securities Litigation Study, at 6 (2004), http://10b5.pwc.com/PDF/2003_STUDY_FINAL.PDF. By 2008, that figure had grown to approximately 48%. See Pricewaterhouse Coopers, 2008 Securities Litigation Study, at 26 (2009), http://10b5.pwc.com/PDF/NY-09-0894%20SECURITIES%20LIT%20STUDY%20FINAL.PDF.

Controlling for other variables, cases with institutional investors as lead plaintiffs result in higher recoveries for shareholders. See Simmons & Ryan, Post-Reform Act Securities Settlements: 2005 Review and Analysis, at 9 (2006), http://securities.cornerstone.com/pdfs/settlements_2005.pdf (hereinafter 2005 Review and Analysis); see also 2009 Mid-Year Update, at 30 ("Cases with an institutional investor serving as lead plaintiff settle for more than settlements without such an institutional lead plaintiff, other things being equal."); Cox & Thomas, Does the Plaintiff Matter? An Empirical Analysis of Lead Plaintiffs in Securities Class Actions, 106 Colum. L. Rev. 1587, 1592 (2006) (finding higher settlements in institutional investor-led cases controlling for estimated provable losses, firm market capitalization, presence of a Securities and Exchange Commission enforcement action, and length of class period).

In addition to evidence that institutional investors obtain better settlements for the injured class members, there is substantial evidence that institutional investors effectively monitor class counsel and negotiate more favorable fee arrangements. For example, in the Cendant litigation, the institutional lead plaintiff negotiated a fee approximately $76 million less than the lowest bid submitted in the trial court's auction, a result that "reflects the broader experience of institutional investors: They are often able to lower counsel fees to one-half to one-third of the historical average of 32% of the recovery." Cox, *supra*, at 1599; see also Fisch, Lawyers on the Auction Block: Evaluating the Selection of Class Counsel by Auction, 102 Colum. L. Rev. 650, 703-714 (2002) (finding negotiation by institutional lead plaintiffs superior to auctions as a method of selecting class counsel). In fact, in settlements over $500 million—those most likely to have an institutional investor as the lead plaintiff—attorneys' fees average only 8% of the settlement amount while attorneys' fees average 25% of the settlement value in settlements less than $500 million. See 2009 Mid-Year Update, at 26.

Finally, institutional investors are motivated to seek corporate-governance reforms as well as accountability from executives, promoting the goal of deterrence. For instance, in the WorldCom case, the New York State Common Retirement Fund made the "highly unusual" demand that outside directors contribute funds from their personal assets to the class-action settlements. 2005 Review and Analysis, at 10;

see also Choi, Fisch, & Pritchard, Do Institutions Matter? The Impact of the Lead Plaintiff Provision of the Private Securities Litigation Reform Act, 83 Wash. U. L.Q. 869, 901, n.91 (2005) ("public pension fund involvement may" make "private litigation function more like public enforcement, which values deterrence and accountability in addition to compensation").

Because of the PSLRA and Sarbanes-Oxley, the lead plaintiffs in a large and growing proportion of securities class actions are institutions motivated to pursue the interests of the plaintiff class as well as the long-term interests of the defendant company and its public investors. See S. Rep. No. 104-98, p. 11. Thus, experience in cases that have been governed by the PSLRA and Sarbanes-Oxley demonstrates that adoption of petitioners' proposed standard is not needed to achieve those statutes' aims. Indeed, continuing promotion of institutional-investor involvement is the best way to achieve those salutary goals without screening out meritorious suits. Cf. Stout, *supra*, at 715 (focusing on changing the choice of lead plaintiff, instead of making it harder for plaintiffs to bring fraud claims, might do much to address false positive error without unduly increasing the risk of false negative error).

CONCLUSION

For these reasons, the Council urges the Court to recognize the enormous importance that Sarbanes-Oxley and the PSLRA have for the investing public. Congress has carefully constructed a regulatory system that encourages legitimate suits to proceed while discouraging those that lack merit. Instrumental to the proper functioning of this system is the investors' ability to carefully analyze the actions of public companies and weigh the merits of filing suit. Experience demonstrates that this regulatory system should not be changed in a manner that would harm those it seeks to protect.

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Petitioners,

v.

RICHARD REYNOLDS, STEVEN LEVAN, JEROME HABER, ET AL.
Respondents.

On Writ of Certiorari to the
United States Court of Appeals for the Third Circuit

BRIEF OF DRI—THE VOICE OF THE DEFENSE BAR AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF THE *AMICUS CURIAE*[1]

Amicus curiae DRI–The Voice of the Defense Bar is an international organization that includes more than 22,000 attorneys involved in the defense of civil litigation. DRI is committed to enhancing the skills, effectiveness, and professionalism of defense attorneys. Because of this commitment, DRI seeks to address issues germane to defense attorneys and the civil justice system, to promote the role of defense attorneys, to improve the civil justice system, and to preserve the civil jury. DRI has long been a voice in the ongoing effort to make the civil justice system more fair, efficient, and—where national issues are involved—consistent.

To promote these objectives, DRI participates as *amicus curiae* in cases that raise issues of fundamental importance to its members and to the judicial system. This case implicates such issues. DRI members routinely defend securities-fraud cases brought under Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. Oftentimes, those cases involve questions about the timeliness of a plaintiff's complaint. As matters now stand, there is a troubling lack of uniformity in how courts determine when the applicable two-year statute of limitations prescribed by 28 U.S.C. § 1658(b) actually begins to run. One possibility, recently adopted by the Ninth Circuit in *Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 876 (9th Cir. 2008), delays commencement of

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[1] No party or counsel for a party authored any part of this brief, and no person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of the brief. The parties have consented to the filing of this brief.

Section 1658(b)'s limitations period beyond the date the plaintiff is deemed to be on "inquiry notice" of his claim for a time sufficient to allow a *reasonable* plaintiff to conduct a *reasonable* investigation—even if the plaintiff himself conducts no investigation whatsoever.

By giving dilatory plaintiffs the benefit of investigations they do not conduct, this "hypothetical-plaintiff" rule unfairly extends the limitations period in favor of the plaintiffs who least deserve the extension. More problematically from DRI's perspective, the hypothetical-plaintiff rule introduces tremendous uncertainty into the limitations analysis, as it requires courts to make all sorts of guesses about the imaginary actions of imaginary litigants. Parties and courts alike benefit from easily discernible rules that clearly govern litigation (and settlement) conduct. DRI participates here to show the inequity and inefficiency of the hypothetical-plaintiff rule, and to urge the Court to reject it.

SUMMARY OF THE ARGUMENT

This case requires the Court to interpret 28 U.S.C. § 1658(b), which prescribes a two-year statute of limitations for private securities-fraud claims. The narrow question presented concerns the nature of a plaintiff's "inquiry notice," which all agree is a prerequisite to the commencement of Section 1658(b)'s limitations period. That question, however, doesn't conclude the limitations inquiry. Instead, it simply leads to a second, more fundamental, issue: Once a plaintiff is deemed to be on inquiry notice, when does the statute actually begin to run? The lower courts have given contradictory answers to that question. Because "any period of limitation is utterly meaningless without specification of the event that

starts it running," *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 199 (1997) (Scalia, J, concurring in part and concurring in the judgment), the Court should take this opportunity to provide necessary guidance.

There are three possible interpretations. Under the first, the statute always commences with the date of inquiry notice, and a plaintiff is charged with investigating the fraud he suspects while the limitations period runs. Under the second, inquiry notice triggers a duty to investigate, and the plaintiff can delay the commencement of the limitations period if—but only if—he actually conducts a diligent investigation. Finally, under the third, whatever the date of inquiry notice, the statute does not begin to run until after the passage of time sufficient to allow a "reasonable investor" to conduct an investigation—even if the plaintiff himself never investigates.

For three reasons, the Court should, at a minimum, reject any rule that would delay beyond the date of inquiry notice the commencement of Section 1658(b)'s limitations period where, as here, the plaintiff does not actually investigate his claim.

1. The "hypothetical-plaintiff" rule contravenes the key policies—both substantive and procedural—that underlie Section 1658(b)'s limitations period. Substantively, the hypothetical-plaintiff rule unfairly prejudices defendants by requiring them to defend stale claims and, more perversely, does so while rewarding dilatory plaintiffs. If it is justifiable to delay the commencement of the limitations period while a plaintiff investigates his claim, the justification rests on the fact that the plaintiff deserves a reward for his diligence. Where, as here, the plaintiff does not investigate, the justification melts

away. Procedurally, the hypothetical-plaintiff rule creates significant uncertainty about the reasonableness of imaginary investors' imaginary investigations. Because the rule has no "anchor in demonstrable fact," *Virginia Bankshares Inc. v. Sandberg*, 501 U.S. 1083, 1092 (1991), but, rather, requires courts to make multiple inferences and guesses about what might have been, it will breed confusion, encourage litigation, and threaten potentially coercive settlements.

2. The hypothetical-plaintiff rule contravenes congressional intent. There is an undeniable—and undisputed—historical link between the statutory term "discovery" and inquiry notice. Given that connection, and because it is "discovery" that starts Section 1658(b)'s limitations clock running, commencement of the limitations period must be tied *in some way* to the plaintiff's receipt of inquiry notice. By rendering inquiry notice a phantom step in the limitations analysis, the hypothetical-plaintiff rule severs the link between "discovery" and inquiry notice and therefore frustrates Congress' design.

3. The hypothetical-plaintiff rule cannot be defended on fairness grounds. This Court has repeatedly held that it is reasonable and appropriate to require plaintiffs to take an active role in investigating their claims—and, in fact, has done so even when the act of investigation does not extend the applicable limitations period. Requiring investigation is doubly appropriate here in light of the fact that the securities-fraud plaintiffs' bar is highly concentrated, sophisticated, and entrepreneurial about finding and prosecuting cases. Given this practical reality, there is no good reason to exempt plaintiffs (or their lawyers) from the duty to conduct an investigation as

condition for delaying the commencement of Section 1658(b)'s time bar.

ARGUMENT

The Court Should Reject Any Rule That Delays Beyond The Date Of Inquiry Notice The Commencement Of Section 1658(b)'s Limitations Period Where The Plaintiff Does Not Actually Investigate His Claim.

There are two issues in this case. This brief will address only the second of them. The first issue—whether there were sufficient "storm warnings" to put the Respondents on "inquiry notice" of their claims—was the focus of the certiorari papers and will undoubtedly garner the lion's share of the attention in the merits briefing, too.

But the second issue is equally important. It is the "so what?" question: Relative to inquiry notice, when does the statute of limitations on a securities-fraud claim actually begin to run? That, it seems, is where the rubber really meets the road. *Cf. Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 199 (1997) (Scalia, J, concurring in part and concurring in the judgment) ("[A]ny period of limitation is utterly meaningless without specification of the event that starts it running."). Unfortunately, the courts of appeals are as hopelessly divided on this second question as they are on the first. As Petitioners say (Pet. Br. 39), the Court can dispose of this particular case without squarely addressing the "so what?" issue. But in light of the circuit conflict, and because the issue is likely to recur with some frequency, the Court would be well-served to consider it now.

In relevant part, the statute-of-limitations provision governing federal securities-fraud claims provides that a plaintiff must sue "not later than ... 2 years after the discovery of the facts constituting the violation." 28 U.S.C. § 1658(b). It is well established, and undisputed here, that the statutory term "discovery" entails not just *actual* discovery, but also *constructive* discovery. *See* Pet. Br. 18-19; *infra* at 19. It is likewise well established, and undisputed here, that constructive discovery incorporates the principle of "inquiry notice." *See* Pet. Br. 20; *infra* at 19-20. The second question here asks how the inquiry-notice gloss on "discovery" affects when Section 1658(b)'s limitations clock actually starts ticking. The answer is not self-evident.

But as usual, there are better answers and worse answers. The courts of appeals have answered this second question in three different ways. Petitioners have described the courts' approaches (Pet. Br. 39, 43, 48), so we will be brief. The first, or "categorical," position holds that Section 1658(b)'s two-year statute of limitations always begins to run from the moment a plaintiff is deemed to be on inquiry notice. Under this categorical rule, the plaintiff is charged with investigating the fraud he suspects while the limitations period runs. *See, e.g.*, *Theoharous v. Fong*, 256 F.3d 1219, 1228 (11th Cir. 2001). Under the second possibility, inquiry notice triggers a duty to conduct a diligent investigation. If the plaintiff fails to discharge that duty, the limitations clock will run from the date of inquiry notice; however, if the plaintiff commences an investigation, the limitations period will not commence until he concludes that investigation. This second approach thus operates like a burden-shifting rule: The limitations period begins to run from inquiry notice unless the plaintiff "counter[s] with a

showing that she fulfilled her corresponding duty of making a reasonably diligent inquiry into the possibility of fraudulent activity." *Young v. Lapone*, 305 F.3d 1, 9 (1st Cir. 2002).

The third position holds that, while inquiry notice may provide some sort of preliminary marker, the statute of limitations itself does not actually begin to run until after the passage of time sufficient to allow a reasonable investor to conduct a diligent investigation to discover the fraud, without respect to whether the *plaintiff himself* actually investigates. *See Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 876 (9th Cir. 2008). Under this third position, "although a plaintiff has an 'obligation of diligence,' the plaintiff need not show the actual exercise of diligence" in order to delay commencement of the limitations period. *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1202 n.20 (10th Cir. 1998) (citation omitted).

This three-way circuit split calls out for this Court's guidance. DRI's purpose here, however, is not so much to advocate that this Court *adopt* any particular one of these positions as to urge the Court to *reject* one of them—namely, the third position, which we'll call the "hypothetical-plaintiff" rule. This modest focus is appropriate for three reasons. First, it is consistent with the Court's incremental approach when considering limitations-rule options—and eliminating bad ones—in analogous contexts. *See, e.g., Klehr*, 521 U.S. at 191-93 (rejecting one among several accrual rules for civil RICO's limitations period); *Rotella v. Wood*, 528 U.S. 549, 554 & n.2 (2000) (same, declining to "settle upon a final rule"). Second, modesty here is consistent with the facts of this particular case. It is apparently undisputed that Res-

pondents never conducted an investigation concerning their claims. *See* Pet. Br. 48; *In re Merck & Co. Sec., Derivative & "ERISA" Litig.*, 543 F.3d 150, 161 (3d Cir. 2008). Accordingly, if this Court concludes that Respondents were on inquiry notice at some date more than two years before they filed their first complaint in November 2003, it can rule their claims untimely without having to choose between the first two positions. Finally, and perhaps most fundamentally, modesty is appropriate because the hypothetical-plaintiff rule is so unusual—and, with respect, so perilous—that it tends by comparison to obscure the differences between the first and second positions. While there are important degrees of variation between options one and two, the hypothetical-plaintiff rule is different in kind, not just degree. In recently adopting it, the Ninth Circuit put itself, in Judge Kozinski's words, "out in left field again." *Trainer Wortham*, 519 F.3d at 865 (Kozinski, C.J., dissenting from denial of rehearing *en banc*).

The Court should reject the hypothetical-plaintiff rule for several reasons. We will consider those reasons in turn.

A. The "Hypothetical-Plaintiff" Rule Contravenes The Substantive And Procedural Policies That Underlie Section 1658(b)'s Limitations Period.

1. The hypothetical-plaintiff rule penalizes defendants while rewarding dilatory plaintiffs.

a. The limitations period applicable to securities-fraud actions should not force plaintiffs "to bring suit prematurely," but it should require them "to bring suit promptly once they have been apprised of their claims (thus securing repose for deserving defendants)." *Young*, 305 F.3d at 9. If the law is too generous in extending the limitations period beyond a plaintiff's receipt of inquiry notice, "the opportunistic use of federal securities law to protect investors against market risk [will] be magnified." *Tregenza v. Great Am. Communications Co.*, 12 F.3d 717, 722 (7th Cir. 1993) (Posner, J.). The sensible goal, in short, is to provide defendants repose, without forcing plaintiffs to speculate, by requiring "the reasonably diligent presentation of tort claims." *United States v. Kubrick*, 444 U.S. 111, 123 (1979) (analyzing the discovery rule applicable to claims brought under the FTCA limitations rule).

The hypothetical-plaintiff rule—which, to repeat, delays the commencement of the limitations period beyond inquiry notice for a time sufficient to allow a hypothetical reasonable investor to conduct a diligent investigation, without respect to whether the plaintiff himself actually investigates—thwarts these policies because it penalizes defendants without aiding deserving plaintiffs. Worse, it encourages bad plaintiff behavior by

giving dilatory plaintiffs the benefit of investigations they do not conduct. The rule necessarily allows a plaintiff to bring a claim that stretches back into the darkening past, even though he spent his "reasonable investigation" time sitting on his hands. *See Brumbaugh v. Princeton Partners*, 985 F.2d 157, 162 (4th Cir. 1993) (discussing the policies underlying the inquiry-notice standard and emphasizing the facts that "[m]emories fade, documents are lost, witnesses become unavailable" as reasons not to delay unreasonably the commencement of the statute). Allowing a do-nothing plaintiff to ride the coattails of a nameless, faceless hypothetical "reasonable" plaintiff just does not make sense.

Considering these incentives, it is reasonable to expect that adoption of the hypothetical-plaintiff rule would usher in an "era of 'ostrichism.'" *See AmerUS Life Ins. Co. v. Smith*, 5 So. 3d 1200, 1208 (Ala. 2008) (quoting *Ex parte Caver*, 742 So. 2d 168, 172 (Ala.1999)) (analyzing the related question whether a fraud plaintiff performed enough investigation to have "reasonably relied" on a false representation). The hypothetical-plaintiff rule allows plaintiffs to bury their heads in the sand and *still* get not just the two years Congress provided in Section 1658(b), but also, as a bonus, the additional time that a reasonable investigation would have taken had it been conducted.

Of course, because the hypothetical-plaintiff rule extends the statute of limitations, it increases the risk of plaintiffs "coerc[ing] settlements" because "aging has improved an originally meritless claim." *Brumbaugh*, 985 F.2d at 162. That much is a given. What makes the hypothetical-plaintiff rule so objectionable, though, is not that it lengthens the limitations period, but that it does

so without regard for individual merit. At best, the hypothetical-plaintiff rule rewards apathy; at worst, it encourages manipulation and opportunism. The rule is in the teeth of elementary notions of equity, including, most notably, the principle that "[o]ne who fails to act diligently cannot invoke equitable principles to excuse that lack of diligence." *Baldwin County Welcome Center v. Brown*, 466 U.S. 147, 151 (1984); *see also, e.g.*, 27A AM. JUR. 2D *Equity* § 93 (1996 & Supp. 2009) ("One of the familiar maxims of equity is that equity aids those who have been vigilant or diligent, not those who sleep or slumber on their rights. In other words, when parties sit idly on their known rights, equity will follow their example." (footnotes omitted)).

If it is justifiable to delay the commencement of a limitations period while a plaintiff performs a reasonable investigation, the rationale for allowing the extra time is that the particular plaintiff deserves a reward for his diligence, just as the fabled ant deserved the grain he harvested and the grasshopper did not. *See* AESOP, *The Ants and the Grasshopper*, *in* AESOP'S FABLES 48-49 (Russell Ash & Bernard Higton, eds. Chronicle Books 1990). By giving grasshopper plaintiffs the same benefit as ant plaintiffs, the hypothetical-plaintiff rule naturally discourages ants in favor of grasshoppers. To make matters worse, unlike the fabled grasshopper, who was rebuked for his laziness when he asked for some of the grain the ant had *actually* stored up against the winter, the hypothetical-plaintiff rule will require courts to determine how much *imaginary* grain some *imaginary* ant would have stored (and how long it would have taken him), and then feed that imaginary grain to the grasshopper. The whole regime rests on a needless fiction

that rewards inequitable conduct with the benefits of equity.

b. The hypothetical-plaintiff rule therefore penalizes every defendant and does so while aiding only those plaintiffs who do not deserve the statute's protection. That equitable imbalance is reason enough to reject the hypothetical-plaintiff rule. It is reason all the more because the alternatives easily avoid these pitfalls. Consider, for instance, the second position described above (*see supra* at 6-7), which functions as a compromise of sorts between, on the one hand, the hypothetical-plaintiff rule, and, on the other, the "categorical" option of starting the two-year clock upon the plaintiff's receipt of inquiry notice and requiring the plaintiff to investigate while the clock runs. The courts that have adopted this intermediate rule allow plaintiffs to delay the commencement of the statute of limitations by initiating and conducting a diligent investigation. If the plaintiff declines to investigate, the statute runs from inquiry notice. This system works well because it uses inquiry notice as a *provisional*—and, where appropriate, *punitive*—start date.

The date is provisional because a plaintiff can delay the commencement of the statute by undertaking a diligent investigation. The statute will begin to run from the *later* of inquiry notice or the completion of the plaintiff's reasonable investigation. If a plaintiff acts on the storm warnings he receives, the statute will wait for him to obtain actual discovery instead of imputing constructive discovery. The provisional date therefore rewards the diligent and should encourage plaintiffs to investigate.

The date can also be punitive because it appropriately penalizes dilatory plaintiffs. Plaintiffs who conduct no investigation are not deserving of the Court's concern—to get the benefit of the discovery rule's equity, the plaintiff must actually do something. *See Wood v. Carpenter*, 101 U.S. 135, 141 (1879) ("A party seeking to avoid the bar of the statute on account of fraud must aver and show that he used due diligence to detect it."). It is worth reiterating, though, that not even the most dilatory plaintiff imaginable is shut out of court altogether; even he has two full years to file suit, which is two-thirds of forever in stock-market years. *See Tregenza*, 12 F.3d at 722 ("Three years is an age in the stock market."). And inquiry notice never punishes a plaintiff who does not deserve it because a plaintiff can avoid the running of the statute simply by investigating.

Indeed, a court actually applying this "compromise" standard would likely find that the vast majority of plaintiffs fit into one of two categories: (1) plaintiffs who receive storm warnings, investigate, actually discover sufficient facts, and file suit; and (2) plaintiffs who do no investigation but sue anyway. A plaintiff in the first class will never have a statute-of-limitations problem under the compromise rule because commencement of the limitations period will wait for the completion of his investigation. A plaintiff in the second class just wants to use the securities laws as after-the-fact insurance and thus doesn't warrant the Court's grace. *Cf. Trainer Wortham*, 519 F.3d at 868 (Kozinski, C.J., dissenting from denial of rehearing *en banc*) ("Plaintiff ... gets the benefit of a 'heads I win, tails you lose' bet: If the investment goes up, he reaps the profit; if it goes down, he gets to recover his losses in court.").

* * *

The hypothetical-plaintiff rule prejudices all defendants in favor of the plaintiffs least entitled to equity's protection. The Court should reject it.

2. The hypothetical-plaintiff rule would confuse judges, prompt inconsistent rulings, and delay resolution of straightforward cases.

Even setting aside the substantive unfairness of rewarding dilatory plaintiffs, the hypothetical-plaintiff rule creates all kinds of procedural problems. At the root of all of those problems is the fact that the rule requires courts to hazard multiple speculative judgments about imaginary conduct by imaginary people. Consider all the guesses a court applying the hypothetical-plaintiff rule has to make to determine when the statute of limitations begins to run. First, of course, it may have to guess about when the plaintiff received inquiry notice. That possibility is inherent in any inquiry-notice regime and is thus common to each of the various approaches. But the commonality ends there. The "categorical" and "compromise" positions entail no further guesswork—only the finding of actual, historical facts. Under the hypothetical-plaintiff rule, by contrast, the guesswork snowballs out of control. Having determined the date of inquiry notice, a court must then guess about (1) what kind of investigation a hypothetical reasonable investor might have conducted, (2) what that hypothetical investigation might have uncovered, and (3) how long the hypothetical investigation might have taken. It is reasonable to assume that there will likely be some variation among judges in how they make their guesses and, further, that

the variation will likely compound with each additional guess. For at least two reasons, the law in this area should encourage fewer guesses, not more.

a. Initially, there is the matter of judicial competency. Counterfactual decisionmaking is not what judges do best, or most often. As relevant here, there is no reason to think that judges are particularly well-equipped—or would want—to imaginatively reconstruct hypothetical investors' hypothetical investigations. By contrast, determining whether an *actual* plaintiff's *actual* investigation was itself "reasonable" would be much more familiar and far less complicated. While it could certainly depend on contextual considerations, those considerations would arise from the particular facts of a real-live investigation. One would assume that the main issues would cluster around determining when the plaintiff started investigating, what the plaintiff did to investigate, and why the plaintiff stopped investigating. And even if individual cases do not involve these common factual patterns, judges are accustomed to considering particular cases on their facts and applying equitable judgment. *See Klehr*, 521 U.S. at 194 (requiring a plaintiff to demonstrate reasonable diligence before asserting fraudulent concealment in civil RICO context); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 208 (1976) (providing that "[a]n expert," such as an accountant, "may avoid civil liability ... by showing that 'after reasonable investigation' he had 'reasonable ground(s) to believe' that the statements for which he was responsible were true and there was no omission of a material fact" (citations omitted)).

The more difficult task—by a long shot—is guessing what facts might have been discoverable at some might-

have-been time by some hypothetical might-have-been plaintiff. The difference between the two approaches is akin to the difference between identifying a sour note in a symphony and determining what note should have been played instead. The critical listener can be flexible to consider all manner of complicated factors that are unique to a particular piece, but actually stepping into the shoes of the composer requires a degree of skill and involvement that even the most conscientious listener probably cannot obtain. It makes much more sense to debate the merits of a tune as it was performed than it does to argue about what an altogether different song—as yet unwritten—might have sounded like.

The Ninth Circuit certainly seemed to recognize the breadth of the test it established in *Trainer Wortham*. The court emphasized that under its rule, while "the question of whether the plaintiff exercised reasonable diligence in investigating the facts underlying the alleged fraud ... necessarily entails an assessment of the plaintiff's particular circumstances," that assessment must be done "from the perspective of a reasonable investor." 519 F.3d at 877. In application, that "assessment" resulted in determining that the statute of limitations had not commenced because a "reasonable investor" would not have discovered the fraud—*even though the investor-plaintiff in that case actually investigated and actually discovered that she had been deceived. See id.* at 878. That "bizarre" result, *see id.* at 867 (Kozinski, C.J., dissenting), is a harbinger of the sorts of outcomes such a flawed test will produce.

b. There is also reason to believe the hypothetical-plaintiff rule could lead to wildly inconsistent results in factually similar cases. Constructing the hypothetical

reasonable plaintiff out of whole cloth and then surmising how his hypothetical investigation might have unfolded will not be an easy task, and, for reasons already explained, judges' imaginative reconstructions are likely to vary widely. As a result, courts around the country will reach ever-diverging opinions about what sort of investigation would be reasonable under the circumstances, how long it would have taken a hypothetical plaintiff to conduct that investigation, and what the investigation might have uncovered. Far from facilitating a uniform "objective" standard, *see Trainer Wortham*, 519 F.3d at 877, the hypothetical-plaintiff rule would institutionalize confusion and set a cacophony of clocks sounding at different times in different courts. Basic considerations of equality, consistency, and predictability counsel avoidance of that result.

This Court has repeatedly emphasized the value of certainty in controlling securities litigation. In refusing to recognize aider-and-abettor liability under Rule 10b-5, for instance, the Court emphasized "the uncertainty of the governing rules," which it feared could lead some companies, "as a business judgment, to abandon substantial defenses and to pay settlements in order to avoid the expense and risk of going to trial." *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 189 (1994). Even more closely analogous is *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723 (1975), in which the Court refused to permit a stock offeree who had never purchased the offered security to maintain a securities-fraud action. In so doing, the Court expressed concern about a rule that would "throw open ... hazy issues of historical fact" and thereby spawn potentially "vexatious litigation." *Id.* at 743. The problem, the Court later summarized, was that "[r]ecognizing

liability to merely would-be investors ... would have exposed the courts to litigation unconstrained by any ... anchor in demonstrable fact, resting instead on a plaintiff's 'subjective hypothesis' about the number of shares he would have sold or purchased." *Virginia Bankshares Inc. v. Sandberg*, 501 U.S. 1083, 1092 (1991). And allowing hypotheses to stand in for facts "would have magnified the risk of nuisance litigation, which would have been compounded both by the opportunity to prolong discovery and by the capacity of claims resting on undocumented personal assertion to resist any resolution short of settlement or trial." *Id.*

Just as the Court refused to "hypothesize" the actions of a "would-be investor[]," it should refuse to hypothesize the actions of a would-be *investigator*. Inferences and guesses about imaginary investigations will only breed confusion, which, in turn, will breed litigation and, in all likelihood, coercive settlements. *Cf. Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 128 S. Ct. 761, 772 (2008) (examining "practical consequences" and finding that "extensive discovery and the potential for uncertainty and disruption in a lawsuit allow plaintiffs with weak claims to extort settlements from innocent companies").

B. The "Hypothetical-Plaintiff" Rule Contravenes The Congressional Intent Embodied In Section 1658(b).

Section 1658(b), again, provides in relevant part that a plaintiff must file his securities-fraud action "not later than ... 2 years after the discovery of the facts constituting the violation." 28 U.S.C. § 1658(b). For present purposes, the important statutory facts are (1) that the limi-

tations period begins to run when a plaintiff "discover[s]" certain facts, and (2) that courts have long understood—and Congress has ratified their understanding—that Section 1658(b)'s requirement of "discovery" incorporates the concept of inquiry notice. The hypothetical-plaintiff rule contravenes the statute because, as we will explain, it necessarily decouples inquiry notice from the commencement of the limitations period.

1. Because Section 1658(b)'s reference to "discovery" undeniably incorporates the principle of inquiry notice, the commencement of the limitations period must be tied—in some way—to the date of inquiry notice.

As noted briefly above, although this Court's decision in *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1990), left the question open, the courts of appeals have unanimously agreed—and it is undisputed here—that "discovery" is not limited to actual discovery, but allows for "constructive discovery," as well. *See* Pet. Br. 18-19; *see also, e.g., Staehr v. Hartford Fin. Serv. Group, Inc.*, 547 F.3d 406, 411 (2d Cir. 2008); *New England Health Care Employees Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 499 (6th Cir. 2003); *Young*, 305 F. 3d at 8; *Menowitz v. Brown*, 991 F.2d 36, 41 (2d Cir. 1993).

And again, it is also established—and undisputed here—that constructive discovery is understood to incorporate the principle of inquiry notice. *See* Pet. Br. 20. Perhaps most significantly, courts so defined constructive discovery, and thus "discovery" itself, before Congress enacted Section 1658(b) in 2002. *See Tregenza*, 12

F.3d at 722 (calling the inquiry-notice gloss on "discovery" a "modest and traditional ... exercise of judicial creativity"); *accord, e.g., Theoharous*, 256 F.2d at 1228; *Berry v. Valence Tech., Inc.*, 175 F.3d 699, 703-04 (9th Cir. 1999); *Great Rivers Co-op of S.E. Iowa v. Farmland Indus., Inc.*, 120 F.3d 893, 896-97 (8th Cir. 1997); *Ockerman v. May Zima & Co.*, 27 F.3d 1151, 1155 (6th Cir. 1994); *Dodds v. Cigna Sec., Inc.*, 12 F.3d 346, 350-51 (2d Cir. 1993); *Menowitz*, 991 F.2d at 41-42; *Howard v. Haddad*, 962 F.2d 328, 329-30 (4th Cir. 1992); *Kahn v. Kohlberg, Kravis, Roberts & Co.*, 970 F.2d 1030, 1042 (2d Cir. 1992); *Topalian v. Ehrman*, 954 F.2d 1125, 1134-35 (5th Cir. 1992).

Against that interpretive backdrop, it is fair to assume that when Congress used the word "discovery" in Section 1658(b), it meant to embody in that term the principle of inquiry notice. *See, e.g., Bragdon v. Abbott*, 524 U.S. 624, 645 (1998). Indeed, here there is more than just assumption. Congress was clearly aware of the inquiry-notice standard, and at least one report summarized that Section 1658(b) was "intended to be consistent with established case law in that the 'discovery' limitations period ... begins to run when the plaintiff is on 'inquiry notice' of a fraud." S. Rep. No. 146, 107th Cong., 2d Sess. 29 (2002) (additional views of eight senators). In any event, none of this is the least bit controversial. Even the Ninth Circuit, despite its adoption of the hypothetical-plaintiff rule, has followed "'every circuit to have addressed the issue since *Lampf*'" and expressly "h[e]ld that either actual or inquiry notice can start the running of the statute of limitations on a federal securities fraud claim." *Trainer Wortham*, 519 F.3d at 874 (citations and quotations omitted). It did so, in part, on the ground

that "Congress implicitly approved of" the post-*Lampf* inquiry-notice case law in Section 1658(b). *Id.* at 875.

The point is simply this: There is an undeniable, direct connection between the statutory term "discovery" and the judicially-created concept of inquiry notice. And because it is "discovery" that starts the limitations clock running, the connection shows that, at the very least, the commencement of Section 1658(b)'s limitations period must be tied in some way to the plaintiff's receipt of inquiry notice. Stated negatively, any severance of the link between "discovery" and inquiry notice that renders the latter a meaningless step in the Section 1658(b) analysis cannot be squared with acknowledged congressional intent.

2. Because the hypothetical-plaintiff rule severs the commencement of the limitations period from the plaintiff's receipt of inquiry notice, it contravenes Congress' intent.

Having established that the receipt of inquiry notice must play a meaningful role in triggering Section 1658(b)'s limitations period, the task becomes determining how the various rules measure up.

Both of the first two options—the "categorical" approach and the "compromise" approach—are broadly consistent with this established link between "discovery" and inquiry notice. The categorical approach comports with the statute because inquiry notice always starts the limitations clock ticking. The syllogism is straightforward: The statute runs from discovery; inquiry notice is discovery; therefore, the statute runs from inquiry notice. The compromise position also jibes with congres-

sional intent because Section 1658(b) can be construed to incorporate a burden-shifting analysis without decoupling "discovery" and inquiry notice. Under this compromise approach, once a plaintiff receives "facts constituting the violation," the plaintiff is on inquiry notice, and can avoid being deemed to have "discover[ed]" those facts—and thereby delay the commencement of the statute of limitations—only by conducting an investigation. Inquiry notice thus starts the limitations clock ticking if the plaintiff does not perform a diligent investigation.[2]

The hypothetical-plaintiff rule, by contrast, cannot be squared with the congressional intent underlying Sec-

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[2] One objection could arise here. In *Lampf*, the Court observed that tolling was "unnecessary" in discovery-rule cases. *See* 501 U.S. at 363. That observation is in no way inconsistent with the practice of delaying the start of the limitations period while the plaintiff investigates. The statute of limitations is not "tolled" during that time because the plaintiff is not deemed to have "discover[ed]" the facts constituting the violation if he is investigating—in other words, the event that triggers the beginning of the two-year clock has not yet occurred. As discussed above, inquiry notice has a punitive aspect to it, and the plaintiff who is actually investigating need not be penalized. If the defendant meets its burden of showing that the plaintiff was on inquiry notice—however defined—then the burden shifts to the plaintiff to show that he conducted a diligent investigation. The statute does not *necessarily* begin to run when the defendant meets its initial burden; it begins to run when the plaintiff's investigation is concluded, if the plaintiff investigates.

In any event, any "tolling"-based objection to the compromise position applies *a fortiori* to the hypothetical-plaintiff rule, for at least two reasons. First, if something like tolling is *possible* under the compromise position, it is *inevitable* under the hypothetical-plaintiff rule. *See, e.g., Sterlin*, 154 F.3d at 1202 n.20. And second, while a tolling-like rule could serve equity under the compromise approach by rewarding a plaintiff's industry, there is no equitable justification for tolling (as the hypothetical-plaintiff rule would) an idle plaintiff's limitations period.

tion 1658(b). By severing "discovery"—and thus the commencement of the limitations period—from inquiry notice, the hypothetical-plaintiff rule departs from the system Congress ratified. The Ninth Circuit's decision in *Trainer Wortham* exemplifies the consequences of this severance. The court there paid lip service to inquiry notice, going so far, in fact, as to say that "inquiry notice can start the running of the statute of limitations on a securities fraud claim." 519 F.3d at 874. But as Judge Kozinski pointed out, the court had only "pretend[ed] to adopt" the inquiry-notice principle while "reject[ing] it in fact." *Id.* at 866 (Kozinski, C.J., dissenting). In the Ninth Circuit's formulation, inquiry notice has no independent bite whatsoever: "Once a plaintiff has inquiry notice, we ask when the investor, in the exercise of reasonable diligence, should have discovered the facts constituting the alleged fraud." 519 F.3d at 876. What role does inquiry notice really play in that analysis? Seemingly none. Why bother with determining when the plaintiff himself received inquiry notice when the ultimate question—when some hypothetical reasonable investor should have investigated long enough to discover the violation—has *nothing to do* with the date of the plaintiff's own inquiry notice? On the Ninth Circuit's view, inquiry notice becomes something of a phantom step in the statute-of-limitations analysis.

And that is a problem, because inquiry notice is no phantom; rather, as already explained, the inquiry-notice principle is part and parcel of the "discovery" to which Section 1658(b) refers. In order to square with Congress' intent, a valid limitations analysis must provide a meaningful role for inquiry notice. The "categorical" and "compromise" approaches outlined above do so. The hypothetical-plaintiff rule does not. It should be rejected.

C. The "Hypothetical-Plaintiff" Rule Is Not Required By Considerations Of Individual Fairness.

There is one loose end to tie up. In this brief we have focused extensively on the role of a particular plaintiff's actual investigation in determining when Section 1658(b)'s statute of limitations begins to run. But is it fair to require a securities-fraud plaintiff to investigate as a condition for delaying the commencement of the limitations period? Yes, for two reasons.

1. *As this Court has repeatedly observed, there is nothing unfair about requiring a plaintiff to investigate his claim.*

In addressing similar statute-of-limitations issues in the past, this Court has required plaintiffs to take an active role in investigating their claims—and, indeed, has done so even when the act of investigating does not buy them any additional time beyond the statutorily prescribed limitations period. In *United States v. Kubrick*, a medical malpractice case arising under the FTCA, the Court held that it was reasonable to require a plaintiff to use his time while the statute of limitations was running to seek "legal or other appropriate advice" about the governing medical standard of care. 444 U.S. at 123-25. Notably, the Court so held despite the acknowledged "technical complexity" of the medical facts at issue in that case. *Id.* at 124. The Court perceived no unfairness in requiring a potential plaintiff to take responsibility for determining whether a legal remedy is available for his known injuries: Making a decision to sue in the face of some uncertainty about the legal merit of one's claim is

"precisely the judgment that other tort claimants must make." *Id.*

Rotella v. Wood imposes a similar burden on civil RICO plaintiffs. The Court there, relying on *Kubrick*, required plaintiffs to investigate the validity of their claims during the limitations period, despite the fact that "a pattern of predicate acts may well be complex, concealed, or fraudulent." *Rotella*, 528 U.S. at 556. The Court reasoned that the important inquiry was not whether the plaintiff could have discovered the claim but whether the plaintiff's ability to investigate was "impaired." *Id.* at 556-57. The inherent complexity of discovering a pattern of racketeering activity did not deter the Court from requiring that a plaintiff investigate.

2. The concentration, sophistication, and entrepreneurship of the securities-fraud plaintiffs' bar confirms the reasonableness of a rule requiring plaintiffs to investigate.

The *Kubrick* and *Rotella* rationales apply *a fortiori* in the securities-fraud context. In neither of those cases did the plaintiffs have an organized bar of specialized lawyers to aid them in the identification and investigation of their claims. At least as an initial matter, the plaintiffs in those cases were on their own. Securities-fraud plaintiffs, by and large, are in much better shape.

As Judge Rakoff recently documented, even in the PSLRA era, securities cases still begin with lawyers looking for clients, not *vice versa*. *See In re Monster Worldwide, Inc. Sec. Litig.*, 251 F.R.D. 132, 135-36 (S.D.N.Y. 2008) (describing a lead plaintiff in that case as "simply the willing pawn of counsel" and calling that

plaintiff's involvement a "sham"). There exists a well-defined cadre of plaintiffs' lawyers who are steeped in securities law, knowledgeable of the standard practices in securities-related industries, and, perhaps most significantly, entrepreneurial about finding and prosecuting securities-fraud cases. Indeed, Respondents' counsel in this case went so far as to urge the district court to take "judicial notice" that "the plaintiffs' bar in the securities area is not asleep at the switch." *See* Pet Br. 45 (quoting J.A. 999).

The degree of concentration and sophistication in the securities-fraud plaintiffs' bar is astounding. According to data compiled by the partnership of Stanford University and Cornerstone Research, nine specialized plaintiffs' firms alone accounted for 82% of all securities class actions settled in 2008:

- Coughlin Stoia Geller Rudman & Robbins LLP[3];
- Barroway Topaz Kessler Meltzer & Check LLP[4];
- Labaton Sucharow LLP[5];
- Milberg LLP (formerly Milberg Weiss Bershad Hynes & Lerach)[6];
- Bernstein Litowitz Berger & Grossman LLP[7];

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[3] *See* http://www.csgrr.com (visited Aug. 14, 2009).

[4] *See* http://www.sbclasslaw.com (visited Aug. 14, 2009).

[5] *See* http://www.labaton.com (visited Aug. 14, 2009).

[6] *See* http://www.milberg.com (visited Aug. 14, 2009).

[7] *See* http://www.blbglaw.com (visited Aug. 14, 2009).

- Cohen Milstein Sellers & Toll[8];
- Stull, Stull & Brody[9];
- Berman DeValerio[10]; and
- Bernstein Liebhard LLP.[11]

See Ellen M. Ryan & Laura E. Simmons, *Securities Class Action Settlements: 2008 Review and Analysis* at 15 (Cornerstone 2009), *available at* http://securities.stanford.edu/Settlements/REVIEW_1995-2008/Settlements_Through_12_2008.pdf. Just four of these firms—Coughlin Stoia, Barroway Topaz, Labaton Sucharow, and Milberg—settled over 58% of the cases. *See id.* In 2007, the percentages were 89% and 66%, respectively, for the same firms. *See id.* What the data show is that this tiny cluster of highly specialized, highly competent firms—three of which have appeared on Respondents' behalf in this case—have a way of identifying and getting involved in the large majority of important securities cases, even those that settle early. The mix of expertise and omnipresence is undeniable, and the Court should consider this reality when gauging the practical effects of any rule it adopts.

With respect to the duty to investigate, the point is simply this: These cases typically are not (as they might initially appear) "tiny investor v. big corporation" affairs. More often than not, the people conducting the investi-

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[8] *See* http://www.cmht.com (visited Aug. 14, 2009).

[9] *See* http://www.ssbny.com (visited Aug. 14, 2009).

[10] *See* http://www.bermanesq.com (visited Aug. 14, 2009).

[11] *See* http://www.bernlieb.com (visited Aug. 14, 2009).

gations of securities cases are lawyers—readily identifiable, expert lawyers—not solitary investors.[12] Securities-fraud plaintiffs don't search for facts, they search for counsel who search for facts—and finding counsel is easy. There is thus no reason to think it the least bit unfair to require a securities-fraud plaintiff to investigate his claim as a condition for delaying the commencement of Section 1658(b)'s two-year limitations period. He will have all the help he needs.

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[12] Indeed, under the PSLRA, securities cases will typically be spearheaded by large, institutional investors. *See* 15 U.S.C. § 78u4(a)(3)(B)(iii)(I)(bb) (establishing a presumption that the plaintiff with the "largest financial interest in the relief sought by the class" will be the lead plaintiff).

CONCLUSION

For the reasons explained in Petitioners' brief, the Court should reverse the Third Circuit's judgment. If the Court chooses to address the question of how the date of inquiry notice affects the running of the statute of limitations, it should hold, at the very least, that where the plaintiff fails to conduct a reasonably diligent investigation upon receipt of inquiry notice, the statute runs from the date of inquiry notice.

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No. 08-905

In The
Supreme Court of the United States

MERCK & CO., INC., ET AL.,

Petitioners,

v.

RICHARD REYNOLDS, ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

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QUESTION PRESENTED

In Section 804 of the Sarbanes-Oxley Act, Congress adopted an explicit statute of limitations and repose for private actions brought under Rule 10b-5, ending sixty years of interpretation based upon judicial common law. *See* 28 U.S.C. § 1658(b). In resolving the appropriate standard, Congress determined that the two year period of limitations should begin, not after inquiry notice, but upon "discovery of the facts constituting the violation."

The question presented is as follows:

Whether the court of appeals erred in failing to apply an actual-discovery standard in determining the accrual date for the statute of limitations.

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INTEREST OF *AMICI CURIAE*[1]

Amici are scholars at American law and business schools, many of whom focus their research and teaching on federal securities regulation. *Amici* have no financial stake in the outcome of this litigation but are interested in ensuring an accurate interpretation of the limitations provision enacted by Section 1658(b). 28 U.S.C. § 1658(b).[2]

This case provides an opportunity for the Court to clarify when the limitations period commences for private actions brought under Section 10(b), 15 U.S.C. § 78j(b), of the Securities Exchange Act of 1934 ("Exchange Act"), and Rule 10b-5, 17 C.F.R. 240.10b-5, promulgated thereunder. The scholars on this brief agree that Congress, in adopting Section 1658(b), did not legislate an inquiry-notice standard, despite the contrary view of numerous lower courts. The purpose of this brief is to provide this Court with a detailed

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[1] This brief was not authored, in whole or in part, by counsel for either party, and no person other than *Amici* and their academic institutions contributed monetarily to the preparation or submission of this brief. This Amicus brief is filed pursuant to the blanket consent executed by counsel for both parties and filed with this Court on July 20, 2009.

[2] In addition to those scholars listed on the front page of the brief, a full list of *Amici*, who joined this brief as individuals and not representatives of any institutions with which they are affiliated, is set forth in the Appendix. *Amici* agree with that central argument that the limitations period begins upon actual knowledge but may not agree with every argument or statement made in this Brief.

analysis of the development of the law concerning the limitations period and its commencement under Rule 10b-5 and the reasons why this Court should hold that investors' time for filing suit begins to run on actual-discovery, rather than on inquiry-notice.

SUMMARY OF ARGUMENT

The court below reversed the district court's decision to dismiss as untimely the action brought by Respondents. In doing so, the court held that Respondents had not been put on "inquiry notice" of the fraud more than two years before the filing of the complaint. Although the ultimate result is correct, the analysis is not. Section 1658(b) specifies an actual-discovery, rather than an inquiry-notice, standard for determining the accrual date of the limitations period for actions brought under Rule 10b-5. 28 U.S.C. § 1658(b).

After more than a half century of judicial monopoly, Congress in 2002 adopted Section 1658(b), thereby creating a statute of limitations and repose for fraud actions brought under Section 10(b) and Rule 10b-5. The five year period of repose represents an outside cut-off that commences at the time of the violation. The two year limitations period begins upon "discovery of the facts constituting" the fraud. *See* 28 U.S.C. § 1658(b). Under the self-evident meaning of this language, the limitations period begins only

when plaintiffs discover – that is, actually know – that they have been defrauded.

The legislative history confirms this actual-knowledge standard. Congress did not intend for investors to use the limitations period to investigate whether a fraud occurred but, rather, to address the "obstacles" that exist "after the fraud is discovered," including the need to unravel the complexities of the violation and address the logistical concerns in bringing a claim, particularly the need to marshal the facts sufficient to meet the heightened pleading standards set out in the Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737 (PSLRA). *See* S. Rep. No. 146, 107th Cong., 2d Sess. 9 (May 6, 2002).

In adopting Section 1658(b), Congress was aware of, and could have resorted to, an inquiry-notice standard to commence the limitations period but did not. First, the securities laws contained a limitations period that begins upon inquiry notice, providing Congress with an appropriate model. *See* Section 13 of the Securities Act of 1933 (1933 Act), 15 U.S.C. § 77m (limitations period begins when "discovery should have been made by the exercise of reasonable diligence").

Second, the inquiry-notice standard was actually used in previous efforts to adopt a statute of limitations for actions under Rule 10b-5. In the aftermath of *Lampf Pleva Lipkind Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991), bills were submitted

in Congress that provided for a statutory limitations period. The proposed legislation incorporated an accrual date that would have commenced the limitations period at the time the violation "should have been discovered through the exercise of reasonable diligence." Securities Investors Legal Rights Act of 1991, H.R. 3185, 102d Cong., 1st Sess. (1991).

Third, the legislative history to Section 1658(b) reveals that Congress knew about the inquiry-notice standard but did not include it in the provision ultimately enacted.

Those contending otherwise assert that there was a "settled understanding" at the time of the adoption of Section 1658(b) arising from *Lampf* and subsequent decisions that actual knowledge was not required to commence the limitations period. This use of the supposed "settled understanding" is not meant to augment or clarify the standard in Section 1658(b) but to contradict the plain language of the statute and the supporting legislative history. This the argument cannot do.

In any event, there was no such "settled understanding." First, this Court in *Lampf* adopted an actual-knowledge, not an inquiry-notice, standard for determining the accrual date of the one year limitations period. This was apparent from this Court's express reliance on Section 9(e) of the Exchange Act, 15 U.S.C. § 78i(e), with its actual-knowledge standard, as the appropriate model, and the explicit

rejection of Section 13 of the 1933 Act, with its inquiry-notice standard.

Lampf's reliance on an actual-knowledge standard also was apparent in the opinion's treatment of equitable tolling. Tolling had allowed courts to ensure fairness by using equity to delay the accrual date where plaintiffs were unaware of the fraud through no fault of their own. *Lampf* concluded, however, that equitable tolling would henceforth be "unnecessary," an approach that could only be understood as a direct consequence of an accrual standard that depended upon plaintiffs' actual knowledge of the fraud. With this Court's ruling that the statute began running only after plaintiffs became aware of the fraud, a tolling doctrine designed to provide additional time to uncover the violation had become superfluous or "unnecessary."

Likewise, in the aftermath of *Lampf*, there was no "settled understanding" that inquiry notice had survived. Commentators concluded that *Lampf* had adopted an actual-knowledge standard. Some courts did the same or explicitly left the issue open. Those courts that ruled otherwise, thereby ignoring this Court's unequivocal language in *Lampf*, did so for varied and sometimes inconsistent reasons. Their confused rationale was accompanied by confused application of the inquiry-notice standard, resulting in wide variations among the circuits.

The multitude of standards conflicted with this Court's goal in *Lampf* of creating a uniform limitations period. These courts compounded the misreading of *Lampf* by severing inquiry notice from equitable tolling. In doing so, they effectively transformed the statute of limitations into a second, shorter period of repose, one that was not susceptible to extension through equitable tolling. Residual concerns over the resulting potential for unfairness caused some later courts relying on inquiry notice to adopt a standard that resembled equitable tolling.

The plain language of Section 1658(b), the legislative history, prior congressional practice, and this Court's analysis in *Lampf*, all compel a conclusion that the limitations period begins only when plaintiffs actually discover the fraud. This actual-knowledge standard also reduces the use of the limitations period (as opposed to the period of repose) to dismiss meritorious cases, an express goal of Congress in adopting Section 1658(b).

The actual-knowledge standard does not interfere with the goals of finality and the elimination of stale claims. Those concerns are addressed through the adoption of a five year statute of repose. As for the assertion that the actual-knowledge standard somehow allows plaintiffs to delay the onset of the limitations period through inactivity, this concern is misplaced.

First, the modern realities of class action securities fraud suits against public companies provide

considerable practical incentive to investigate the mere suspicion of a violation. Any delay in investigation could result in the expiration of the period of repose or the failure to meet the heightened pleading standards contained in the PSLRA.

The possibility of deliberate inactivity is also belied by the reality of class action securities litigation. The PSLRA sought to, and did, increase the role of institutional investors, those plaintiffs with the resources available to conduct their own investigations. In these circumstances, law firms that delay investigating the possibility of fraud may find themselves at a disadvantage. Firms aware of the fraud and able to discern the applicable class will be in a position to identify lead plaintiffs and use private ordering to increase the potential for designation as lead counsel. *See* 15 U.S.C. § 78u-4.

Second, a legal standard that determines actual knowledge through reference to the entire class will essentially eliminate even the possibility of the strategic use of inactivity. In the context of class actions against public companies for securities fraud, actual knowledge is most appropriately considered through resort to the information known to the market. To the extent known in this fashion, plaintiffs will be unable to rely on their own unawareness to delay the onset of the limitations period. This also provides plaintiffs with an additional incentive to investigate even the possibility of fraud in order to discover facts known to the market.

The application of the actual-knowledge standard under the facts of this case illustrates wisdom of the standard and the potential harm that can result from the use of inquiry notice.

With the release of the data in the Gastrointestinal Outcomes Research study in 2000, the market was made aware of two competing, antithetical explanations for the harmful cardiovascular events incurred by those participants taking VIOXX. The data was explained either by the risk of taking VIOXX or the benefit of taking Naproxen ("Naproxen hypothesis"). The market likewise knew that both hypotheses were unproven. Even the warning letter from the FDA left the market's awareness apparently unaltered.

Had Respondents been obligated to bring a claim under an inquiry-notice standard, before possessing evidence purporting to show that the Naproxen hypothesis was false or that Petitioner Merck & Co. (Merck) lacked a reasonable basis for the hypothesis, they would have confronted an untenable choice. They either could have allowed the limitations period to expire on a potentially meritorious claim or they could have filed a fraud action based upon little more than the existence of two competing hypotheses, thereby risking dismissal.

This use of the inquiry-notice standard on the one hand permits the elimination of potentially meritorious claims and on the other hand encourages the filing of meritless claims. Meritless claims do more

than waste resources. They expose plaintiffs and their counsel to the possibility of sanctions under Fed. R. Civ. P. 11. *See* 15 U.S.C. § 78u-4(c) (making mandatory consideration of sanctions under Rule 11 upon final adjudication of a securities fraud action). These concerns are greatly reduced through a limitations period that begins with actual knowledge rather than inquiry notice.

In this case, Respondents should not have been subjected to the two year limitations period until the market had evidence purporting to show that the Naproxen hypothesis was false or that Merck lacked a reasonable basis for the hypothesis. Section 1658(b) does not require more.

ARGUMENT

I. Congress Adopted a Statute of Limitations and Statute of Repose for Private Actions Brought Under Rule 10b-5 and Began the Limitations Period at the Time Plaintiffs Actually Discovered the Fraud

For over six decades, the matter of a limitations period under Rule 10b-5 was left to the courts. Congress altered this state of affairs with the adoption of the Corporate and Criminal Fraud Accountability Act of 2002, known as the Sarbanes-Oxley Act (SOX). *See* Pub. L. No. 107-204, 116 Stat. 745, July 30, 2002. With a series of corporate scandals providing a catalyst, Congress sought to increase accountability

for those most responsible for the financial disclosure process. *See generally* J. Robert Brown, Jr., *Criticizing the Critics: Sarbanes-Oxley and Quack Corporate Governance*, 90 Marq. L. Rev. 309 (2006).

As part of the reforms, SOX strengthened private law enforcement by providing defrauded investors with additional time to file claims under the anti-fraud provisions of the Exchange Act. Specifically, Section 804 of SOX amended 28 U.S.C. § 1658(b) to provide for both a longer period of limitations (two years) and a longer period of repose (five years). Pub. L. No. 107-204, Title VIII, § 804, 116 Stat. 745, 801 (2002).

The five year period of repose begins after the violation, creating a firm cut-off date for any fraud action. The two year limitations period starts upon "discovery of the facts constituting" the fraud. 28 U.S.C. § 1658(b). Under the self-evident meaning of this language, the limitations period begins only when plaintiffs discover – that is, actually know – that they have been defrauded. The language is identical to the text of Section 9(e) of the Exchange Act which also relies on actual knowledge to determine the accrual date of the limitations period.[3] *See*

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[3] This is confirmed by references in the legislative history to a discovery, rather than an inquiry-notice, standard. *See generally*, Lyman Johnson, *Securities Fraud and the Mirage of Repose*, 1992 Wis. L. Rev. 607, 622-23. Likewise courts have acknowledged the actual-discovery standard in Section 9(e). *See Tregenza v. Great Am. Communications Co.*, 12 F.3d 717, 721

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15 U.S.C. § 78i(e) (requiring action to be brought within one year of "discovery of the facts constituting the violation"). Section 1658(b) says nothing about notices, storm warnings, the need to investigate, or any obligation to inquire.

As this Court has emphasized repeatedly, the plain language of the securities statute is enough to resolve the matter. *See Landreth Timber Co. v. Landreth*, 471 U.S. 681, 687 (1985); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 200-201 (1976); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 330 (2007) (Scalia, J., concurring) (in interpreting amendments to the federal securities laws, "it is our job to give that phrase its normal meaning.").

Resort to the legislative history, while unnecessary, nonetheless confirms the intent of Congress to adopt an actual-knowledge standard. In the description of the law, the Senate Report refers to the discovery standard, making no mention of inquiry notice. *See* S. Rep. No. 146, 107th Cong., 2d Sess. 12 (May 6, 2002). Moreover, the Report's discussion of Section 804 states that the limitations period ran not upon the suspicion of fraud, but "from the moment [fraud victims] *know* that they have been cheated." S. Rep. No. 146, at 9 (emphasis added). The period is

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(7th Cir. 1993), *cert. denied*, 511 U.S. 1085 (1994); *Walck v. American Stock Exchange, Inc.*, 687 F.2d 778, 792 (3d Cir. 1982), *cert. denied*, 461 U.S. 942 (1983); *see also Rosenberg v. Hano*, 121 F.2d 818, 821 (3d Cir. 1941).

necessary "after the fraud is discovered" to allow investors enough time to address the "obstacles" associated with bringing a claim, particularly the "complexities of how the fraud was executed" and the heightened pleading standards set out in the PSLRA. *Id.*

The plain language is even more compelling given congressional awareness of the inquiry-notice standard and the failure of Congress to adopt it. First, the securities laws contain an explicit inquiry-notice standard. *See* Section 13 of the Securities Act of 1933, 15 U.S.C. § 77m (limitations period begins to run after discovery or "after such discovery should have been made by the exercise of reasonable diligence."). In other words, Congress had a readily available model if it wanted to promulgate an inquiry-notice standard but did not use the text in Section 13. *See Central Bank, N.A. v. First Interstate Bank, N.A.*, 511 U.S. 164, 176 (1994) (pointing to other statutory examples not in the federal securities laws and noting that "Congress knew how to impose aiding and abetting liability when it chose to do so.").[4]

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[4] There are reasons why inquiry notice may be appropriate under Section 13 of the 1933 Act but not under Rule 10b-5. Section 13 applies the inquiry-notice standard to causes of action under both Sections 11 and 12(a)(2) of the 1933 Act, 15 U.S.C. §§ 77k & 77l(a)(2), neither of which requires proof of scienter. *See* 2 Thomas Lee Hazen, TREATISE ON THE LAW OF SECURITIES REGULATION § 7.10 at p. 315 (6th ed. 2009). In contrast, claims under Rule 10b-5 do require a showing of scienter, elevating the burden of proof imposed on plaintiffs and

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Second, the inquiry-notice standard actually was considered by lawmakers during their previous efforts to enact a statute of limitations for actions under Rule 10b-5. In the aftermath of *Lampf,* bills were submitted in Congress that provided for a statutory limitations period. The proposed legislation incorporated an accrual date that would have commenced the limitations period at the time the violation "should have been discovered through the exercise of reasonable diligence." Securities Investors Legal Rights Act of 1991, H.R. 3185, 102d Cong., 1st Sess. (1991); *see also* S. 1533, 102d Cong., 1st Sess. (1991). Congress failed to enact the proposed law as drafted.

Third, the legislative history to Section 1658(b) shows that Congress was fully aware of the inquiry-notice standard but did not include it in the version ultimately enacted. *See* S. Rep. No. 146, at 29.[5]

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necessitating a more lenient accrual-date standard. *See Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976).

[5] There is a reference to the inquiry-notice standard in a statement attached to the Report of the Senate Judiciary Committee by a minority of its members. Reports by a minority of members often contain views inserted for strategic purposes and, for that reason, are entitled to little weight. *See* McNollgast, *Legislative Intent: The Use of Positive Political Theory in Statutory Interpretation*, 53 Law & Contemp. Probs. 3, 28-29 (1994) (given an incentive to act strategically, "a statement by a member acting as an individual, and minority views and reports, should carry no weight in statutory interpretation."). The statements here are particularly problematic since most of those attesting to the minority views also voted to delete the limitations

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The plain meaning of the statutory language, the legislative history, and the prior actions of Congress, all compel the same conclusion: Congress meant what it said. The limitations period does not begin to run upon inquiry notice but upon actual discovery of the facts constituting the fraud.

II. Section 1658(b) Cannot Be Altered by a "Settled Understanding" That Would Contradict the Plain Language of the Statute; There Was No "Settled Understanding" That the Language in Section 1658(b) Was Rewritten to Include Inquiry Notice

Those contending otherwise assert that there was a "settled understanding" at the time of the adoption of Section 1658(b) arising from *Lampf* and lower court decisions that actual knowledge was not required to commence the limitations period. The contention does not use the supposed "settled understanding" to augment or clarify the statute but to contradict the plain meaning. The actual-knowledge standard would be entirely undone by a limitations

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period. *See* S. Rep. No. 146, at 22 & 31 (seven of the eight members on the minority report voted in favor of second degree amendment that would strike statute of limitations provision in substitute amendment). While these views are entitled to no weight in assessing the language of Section 1658(b), they do demonstrate awareness of the inquiry-notice standard by the Committee.

period said to run upon mere suspicion of fraud. A "settled understanding" cannot be used to rewrite the statute in this manner. *See Jimenez v. Quarterman*, 129 S. Ct. 681, 685 (2009) (applying a settled understanding "which comports with the most natural reading of the statutory text.").

In any event, there was no "settled understanding" about the availability of inquiry notice at the time Congress adopted Section 1658(b). First, this Court in *Lampf* expressly relied on an actual-knowledge standard, not an inquiry-notice, standard for determining the accrual date of the one year limitations period adopted in that case. 501 U.S. at 364.

Second, in the aftermath of *Lampf*, there was no "settled understanding" among courts and commentators that inquiry notice had survived. Commentators concluded that *Lampf* had adopted an actual-knowledge standard. Some courts did the same or explicitly left the issue open. Those courts that ruled otherwise showed little consistency in how they arrived at this conclusion. Moreover, courts compounded the misreading of *Lampf* by severing inquiry notice from equitable tolling, effectively transforming the limitations period into a second, shorter statute of repose, one that was not susceptible to extension in the event of unfairness.

a. This Court in *Lampf* Adopted An Actual-Knowledge Standard for Determining the Accrual Date of the One Year Limitations Period

This Court in *Lampf* ended reliance on state law as the source of the limitations period under Rule 10b-5. *Lampf* also eliminated the inquiry-notice standard and, with it, its counterpart, equitable tolling. By adopting an actual-knowledge standard, equitable tolling had become "unnecessary," as this Court recognized. *See* 501 U.S. at 363. The importance of the *Lampf* decision and the implications for this case can be seen most clearly in the pre-*Lampf* development of the judicial limitations period.

i. Before This Court's Opinion in *Lampf*, Lower Courts Relied on an Inquiry-Notice Standard That Could be Modified Through the Application of Equitable Tolling

Judicial development of the limitations period prior to *Lampf* was "often chaotic." *Lampf*, 501 U.S. at 367 (Stevens, J., dissenting). Nonetheless, the discord masked a substantial amount of harmony on important aspects of the analysis. Until the Third Circuit's *en banc* decision in *Data Access*,[6] all circuits

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[6] *In re Data Access Sys. Sec. Litig.*, 843 F.2d 1537, 1547 (3d Cir. 1988) (en banc), *cert. denied sub nom. Vitiello v. I. Kahlowsky & Co.*, 488 U.S. 849 (1988).

addressing the issue agreed that the limitations period was determined through reference to state law. Courts sought the most analogous state cause of action and took from it the relevant time period.

The courts likewise agreed that, while state law dictated the applicable time period, federal law determined when it would accrue or begin to run. In addressing the start date, they rejected arguments that the period should begin at the time the fraudulent behavior occurred. *See Vanderboom v. Sexton*, 422 F.2d 1233, 1240 (8th Cir.), *cert. denied*, 400 U.S. 852 (1970). Rather, they opted for an inquiry-notice standard that effectively lengthened the limitations period. *See Maggio v. Gerard Freezer & Ice Co.*, 824 F.2d 123, 128 (1st Cir. 1987).

The need for inquiry notice arose out of another area of judicial consensus. The time periods borrowed from state law were routinely characterized not as a statute of repose but as a statute of limitations. A statute of repose would have established a firm cut-off date for any fraud action under Rule 10b-5. Without an objective outside limit, an actual-knowledge standard carried with it the potential risk that plaintiffs would rely on their own inactivity to delay the accrual date, conflicting with the goals of finality and elimination of stale claims. *See Arneil v. Ramsey*, 550 F.2d 774, 780 (2d Cir. 1977) ("The statutory period . . . [does] not await appellant's leisurely discovery of the full details of the alleged

scheme.") (quoting *Klein v. Bower*, 421 F.2d 338, 343 (2d Cir. 1970)).[7]

Inquiry notice promoted finality by starting the statute irrespective of the plaintiff's actual knowledge. It also, however, raised concern over possible unfairness. Reliance on a standard that did not require actual knowledge of the fraud to commence the limitations period posed some risk that plaintiffs would not learn of the violation until after expiration of the applicable time period.

The courts addressed the fairness concerns through resort to equitable tolling. Equity allowed a delay in the onset of the limitations period where plaintiffs, "without any fault or want of diligence," were unable to discover the existence of the fraud. *Bailey v. Glover*, 88 U.S. (21 Wall) 342, 348 (1875). Where the fraud was not subject to discovery as a result of concealment, equity could dispense with the need for diligence. *See* David S. Ruder & Neil S. Cross, *Limitations On Civil Liability Under Rule 10b-5*, 1972 Duke L. J. 1125, 1143 ("The soundest interpretation seems to be that where a person has been

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[7] The use of inactivity to delay the onset of the limitations period is not, and likely never was, a significant concern with respect to class actions brought under Rule 10b-5. *See* discussion *infra*, Section III. Nonetheless, the risk of inactivity, however slight, was compounded during the period preceding this Court's opinion in *Lampf* by the absence of a statute of repose and the concomitant concern over finality. The inclusion in Section 1658(b) of a statute of repose eliminates that concern. 28 U.S.C. § 1658(b).

injured by fraud, his lack of diligence in pursuing his rights, which normally would bar his claim, will be excused by a defendant's fraudulent concealment.").

In the period preceding intervention by this Court in *Lampf*, therefore, courts routinely relied on inquiry notice to determine the accrual date, an approach designed to ensure finality by minimizing plaintiffs' ability to control the onset of the limitations period. This was particularly necessary given the absence of a statute of repose. The potential for unfairness was mitigated through equitable tolling. The doctrine left to the courts, rather than plaintiffs, the determination of whether equity mandated additional time.

ii. *Lampf* Created a Federal Statute of Limitations That Relied on an Actual-Knowledge Rather Than Inquiry-Notice Standard to Begin the Limitations Period, Thereby Rendering Equitable Tolling "Unnecessary"

Lampf ended reliance on state law as the source of the relevant time period for actions brought under Rule 10b-5 but continued to maintain the balance between the need for finality and the risk of unfairness. This Court looked to federal law, adopting the "1-and-3-year structure" commonly found in the securities laws. *See Lampf*, 501 U.S. at 335 (noting this structure found in Section 13 of the 1933 Act, 15 U.S.C. 77m, and Sections 9(e) and 18(c) of the Exchange Act, 15 U.S.C. §§ 78i(e) & 78r(c)). The

shorter period served as a statute of limitations and the longer one as a statute of repose, subjecting actions under Rule 10b-5 to a firm cut-off date for the first time. *See Lampf*, 501 U.S. at 360.

Lampf did more than resolve the applicable time periods, however. The opinion also rejected inquiry notice in favor of actual knowledge. This result is evident both from the reliance on Section 9(e) of the Exchange Act as the applicable model for the limitations period and from this Court's characterization of equitable tolling as "unnecessary." 501 U.S. at 363.

The one year, three year structure adopted by this Court in *Lampf* appeared in three separate sections of the securities laws. Had this Court been concerned only with the applicable time periods, there would have been no need to examine differences among these sections. Instead, this Court acknowledged the point raised by the Securities and Exchange Commission in its Amicus brief that "the various 1- and -3-year periods contained in the 1934 and 1933 Acts differ slightly in terminology." *Lampf*, 501 U.S. at 364.

The SEC's amicus brief specifically pointed out that, unlike claims subject to Sections 9(e) and 18(c) of the Exchange Act, those brought under Section 13 of the 1933 Act had to be "filed within one year of actual or constructive discovery. . . ." Brief for the Securities and Exchange Commission as Amicus Curiae, *Lampf Pleva Lipkind Prupis & Petigrow v. Gilbertson*, No. 90-333, 1990 U.S. S. Ct. Briefs LEXIS

352, December 5, 1990, *38.[8] Aware that Section 13 relied upon a constructive discovery standard while Section 9(e) did not, the Court opted for the latter. *See Lampf,* 501 U.S. at 364 n. 9 ("To the extent that these distinctions in the future might prove significant, we select as the governing standard for an action under § 10(b) the language of § 9(e) of the 1934 Act. . . .").

Rejection of the constructive discovery standard in favor of actual knowledge dictated what followed with respect to equitable tolling. Tolling became "unnecessary" since "by its terms, [the limitations period] begins after discovery of the facts constituting the violation. . . ." *Id.* at 363. The characterization as "unnecessary" could only be understood as an ineluctable consequence of an accrual standard that depended upon actual awareness of the fraud. Where plaintiffs knew they had been defrauded, a tolling doctrine designed to provide additional time to uncover the violation had become superfluous or "unnecessary." As one commentator put it: "Equity is not

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[8] The SEC likewise emphasized the constructive discovery standard employed in Section 13 in its analysis of the case law that preceded *Lampf. See* Brief for the SEC, 1990 U.S. S. Ct. Briefs LEXIS 352, at 39 (noting that the Seventh Circuit had "mistakenly thought that the Third Circuit [in *Data Access*] had selected Section 13 of the 1933 Act. . . . But that provision includes a constructive discovery limitation on the one-year period, in conflict with the choice made by *Data Access*").

summoned when its corrective nudges are unneeded."[9]

The approach benefited plaintiffs. *Lampf* subjected plaintiffs to a short, one year limitations period and, for the first time, a period of repose. In turn, they received the benefit of a greatly simplified standard for obtaining delay in the accrual date of the limitations period. Rather than establish the elements of equitable tolling, plaintiffs only needed to show unawareness of the fraud. *See* Lyman Johnson, *Securities Fraud and the Mirage of Repose*, 1992 Wis. L. Rev. 607, 625 ("[A]lthough *Lampf* shortened the ostensible limitations period for Rule 10b-5 claims to one-year, the actual amount of time for beginning an action – measured from the date of wrongdoing – may have been lengthened because the period is now triggered only by actual, not imputed, discovery."). The standard reduced the risk that the one year period would be used to dismiss meritorious claims.

The actual-knowledge standard did not mean that this Court had abandoned the traditional concerns over finality and elimination of stale claims. This Court addressed those through the importation of the period of repose from Section 9(e). In doing so, *Lampf* ensured that an action under Rule 10b-5 would expire three years after the fraud, even if plaintiffs remained unaware or the wrongdoers

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[9] Lyman Johnson, *Securities Fraud and the Mirage of Repose*, 1992 Wis. L. Rev. 607, 628.

continued to conceal.[10] In other words, this Court chose to address the need for finality not through an inquiry-notice standard that caused a more rapid onset of the limitations period, but through a firm cut-off date that was not dependent upon the actions of the plaintiffs or the wrongdoers.

Lampf, therefore, adopted an actual-knowledge standard. To the extent that Congress relied on the analysis in *Lampf*, it supports the plain language of Section 1658(b).

b. There Was No "Settled Understanding" Among Lower Courts and Commentators That This Court in *Lampf* Intended to Adopt an Inquiry-Notice Standard That Was Incorporated by Congress into Section 1658(b)

For Congress to have adopted a settled understanding, there needs to be a settled understanding. This requires a high degree of agreement among commentators and courts. *See Director v. Greenwich Collieries*, 512 U.S. 267, 276 (1994) (applying notion of settled understanding where courts and commentators

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[10] The determination was not without dissent. Justices Kennedy and O'Connor viewed the three year period of repose as excessively short and likely to result in unfairness. *See Lampf*, 501 U.S. at 379 (Kennedy, J., dissenting) ("The Court's decision today forecloses any means of recovery for a defrauded investor whose only mistake was not discovering a concealed fraud within an unforgiving period of repose.").

"almost unanimously agreed" that the meaning was "settled" and Congress indicated that it "shared this settled understanding"). Such a settled understanding did not exist at the time Congress adopted Section 1658(b).

In the aftermath of *Lampf*, and notwithstanding its unambiguous adoption of an actual-knowledge standard, through the adoption of Section 1658(b), opinion divided over the appropriate standard for determining the accrual date for the one year limitations period applicable to actions under Rule 10b-5. Commentators viewed *Lampf* as having replaced inquiry-notice with an actual-knowledge standard. *See* Johnson, *Securities Fraud and the Mirage of Repose*, 1992 Wis. L. Rev. at 620; Lewis D. Lowenfels and Alan R. Bromberg, *SEC Rule 10b-5 and Its New Statute of Limitations: The Circuits Defy the Supreme Court*, 51 Bus. Law. 309, 313 (Feb. 1996); Richard H. Walker and J. Gordon Seymour, *Recent Judicial and Legislative Developments Affecting the Private Securities Fraud Class Action*, 40 Ariz. L. Rev. 1003, 1009 (1998).

A handful of district courts relied on *Lampf* either to reject inquiry notice or to question its validity.[11] The Third Circuit arguably retained an

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[11] *See Slavin v. Morgan Stanley & Co.*, 791 F. Supp. 327, 332 (D. Mass 1992); *In re Digital Microwave Corp. Sec. Litig.*, 1992 U.S. Dist. LEXIS 18469 (N.D. CA Oct. 19, 1992); *see also City of Painesville v. First Montauk Fin. Corp.*, 178 F.R.D. 180, 194 (N.D. Ohio 1998).

actual-knowledge standard,[12] while the Ninth Circuit openly expressed doubts about the survival of the inquiry-notice standard but left the matter unresolved.[13]

Those courts that opted for an inquiry-notice standard were themselves divided. They could not agree on the reasons for rejecting actual knowledge.[14]

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[12] The actual-knowledge standard was adopted in *In re Data Access Systems*, 843 F.2d at 1550 (noting that proper limitations period is "one year after the plaintiff discovers the facts constituting the violation"). *See also Gruber v. Price Waterhouse*, 911 F.2d 960, 964 n. 4 (3d Cir. 1990) ("Data Access actually relied upon the Securities Exchange Act of 1934 which does not provide for inquiry notice."). While the Third Circuit hinted at an inquiry-notice standard before the adoption of SOX, *see Mathews v. Kidder, Peabody & Co., Inc.*, 260 F.3d 239, 251 (3d Cir. 2001), the issue was sufficiently open to cause the Third Circuit to determine, after enactment of Section 1658(b), that "[w]e have not . . . decided the precise standard [to determine when the limitations period begins] in the context of a securities fraud claim." *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1318 (3d Cir. 2002).

[13] *See Berry v. Valence Tech., Inc.*, 175 F.3d 699, 704 (9th Cir.), *cert. denied*, 528 U.S. 1019 (1999). *See also Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 951 (9th Cir. 2005). The Circuit only resolved the issue in 2008. *See Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 869 (9th Cir. 2008), *petition for cert. pending*, No. 07-1489 (filed May 27, 2008).

[14] Their refusal to adopt actual knowledge caused two commentators to rhetorically ask: "[W]hy [are] the federal circuit courts . . . ignoring the apparently clear mandate of the Supreme Court in *Lampf* and opting for an 'inquiry notice' trigger. . . ." Lewis D. Lowenfels and Alan R. Bromberg, *SEC Rule 10b-5 and Its New Statute of Limitations: The Circuits Defy the Supreme Court*, 51 Bus. Law. 309 (Feb. 1996).

One court, for example, found the inquiry-notice standard within the meaning of the word "discovery" in Section 9(e), *see Menowitz v. Brown*, 991 F.2d 36, 41 (2d Cir. 1993) (per curiam opinion concluding that the term "discovery" included "constructive or inquiry notice, as well as actual notice."), a conclusion rejected out of hand by another. *See Tregenza v. Great Am. Communications Co.*, 12 F.3d 717, 721 (7th Cir. 1993), *cert. denied*, 511 U.S. 1085 (1994) ("Section 9(e), read literally, requires actual knowledge to set the statute of limitations running.").

Sometimes courts acted without explanation. *See Howard v. Haddad*, 962 F.2d 328, 330 (4th Cir. 1992) (quoting the language in *Lampf* that the statute begins to run "within one year after the discovery of the facts constituting the violation," but, without additional reasoning, concluding that the relevant standard was "reasonable diligence"). In other instances, they looked to the wrong statute for controlling law. *See Great Rivers Coop. v. Farmland Industries, Inc.*, 120 F.3d 893, 896 (8th Cir. 1997) (citing *Lampf* for the proposition that the "applicable statute of limitations for federal securities fraud claims is the one-year period set forth in section 13 of the 1933 Securities Act"); *see also Ritchey v. Horner*, 244 F.3d 635, 638 (8th Cir. 2001) ("The time period in which an aggrieved party must bring an implied private cause of action under § 10(b) and Rule 10b-5 is governed by § 13 of the Securities Act of 1933.").

A number of courts conceded that Section 9(e) employed an actual-discovery standard but discounted this Court's reliance on the provision. The

Tenth Circuit determined that *Lampf* had intended to absorb the time period from Section 9(e), but not the accrual standard. *See Anixter v. Home-Stake Production Co.*, 947 F.2d 897, 899 (10th Cir. 1991) (*amending*, 939 F.2d 1420 (10th Cir. 1991)), *vacated sub nom., Dennler v. Trippet*, 503 U.S. 978 (1992).

The Seventh Circuit in *Tregenza* described this Court's reference to Section 9(e) in *Lampf* as "pointing both ways" and "not much help." 12 F.3d at 718.[15] Having dispensed with any need to follow the reasoning in *Lampf*, Judge Posner acknowledged that the moment was ripe for "judicial creativity," causing him to rhetorically ask: "The precise question, then, is not: Does section 9(e) incorporate the rule of inquiry notice? It is: Are courts free to apply to the section the judge-made doctrine of inquiry notice, long applied in fraud cases outside as well as inside the securities field?" Although purporting to look to congressional intent for guidance, Judge Posner resolved the issue selectively and discounted inconsistent precedent within his own circuit.[16] It was, as another circuit

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[15] *See* Lowenfels & Bromberg, 51 Bus. Law. at 316 (describing the Seventh Circuit's conclusion in *Tregenza* that *Lampf* "contains dicta pointing both ways" on the intended use of Section 9(e) as a position that "seems dubious").

[16] Judge Posner purported to rely on a likely congressional intent that the implied limitations period for Rule 10b-5 would be treated identically to the express limitations period in Section 13 of the Securities Act. Section 13 relied on an inquiry-notice standard. *See Tregenza*, 12 F.3d at 722 ("If, as Congress plainly believed, inquiry notice makes sense for fraud in the sale of stock, it makes sense when the fraud is challenged under the

(Continued on following page)

described, a decision based upon "policy grounds." *Berry v. Valence Technology, Inc.*, 175 F.3d 699, 704 n.6 (9th Cir. 1999), *cert. denied*, 528 U.S. 1019 (1999).

The confused rationale was only outdone by the confused application.[17] The standards, however, all shared a common attribute. They tolerated circumstances where the limitations period (as opposed to the period of repose) could expire on meritorious cases before plaintiffs acquired actual knowledge of the fraud.

The variations among the circuits were themselves inconsistent with *Lampf*. This Court had sought to erase the confusion of multiple standards under state law by establishing a single, uniform federal standard, one that began upon actual knowledge. *See* 501 U.S. at 355 ("we agree that a uniform federal period is indicated").

The lower courts compounded the wrong by misreading *Lampf* to allow for inquiry notice shorn of

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rule rather than under the statutes."). But *Tregenza* also upheld the elimination of equitable tolling. *Id.* at 720-721. An earlier case in the same circuit indicated that when Congress used inquiry notice in Section 13, it had not intended to "obliterate" equitable tolling. *See Short v. Belleville Shoe Manufacturing Co.*, 908 F.2d 1385, 1391 (7th Cir. 1990), *cert. denied*, 501 U.S. 1250 (1991).

[17] Petitioners have set out the assorted standards, *see* Petition for a Writ of Certiorari and Appendix, at 18-25, *Merck & Co., Inc. v. Reynolds* (No. 08-905), as has the government in a related case. *See* Brief for the United States as Amicus Curiae, at 14-17, *Trainer Wortham & Co. v. Betz* (No. 07-1489).

equitable tolling. *Lampf's* characterization of equitable tolling as "unnecessary" followed ineluctably from the adoption of an actual-knowledge standard. These courts, however, severed the two doctrines, retaining inquiry notice but eliminating the safety valve of equitable tolling.[18] The approach effectively transformed the shorter limitations period into a second period of repose, one that could not be extended through equitable tolling. The approach increased the risk of unfairness and the dismissal of meritorious cases.

These results were not consistent with this Court's decision in *Lampf* and its adoption of an accrual standard that rendered equitable tolling "unnecessary."[19] They were contrary to the views of a number of courts and many commentators and among themselves sometimes inconsistent. Congress in adopting Section 1568(b) cannot be said to have included a "settled understanding" in these circumstances, particularly one that would contradict both the plain language of the statute and this Court's plain ruling in *Lampf*.

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[18] This separation of the two doctrines also was inconsistent with the intent of Congress when it adopted the express inquiry-notice standard in Section 13 of the 1933 Act. *See supra* note 16.

[19] Apparent concerns over the resulting potential for unfairness subsequently caused some courts relying on inquiry notice to adopt a standard that resembled equitable tolling. *See* Brief for the United States as Amicus Curiae, at 15, *Trainer Wortham & Co. v. Betz* (No. 07-1489).

III. An Actual-Discovery Standard Reduces the Risk of Dismissing Meritorious Claims and Does Not Encourage Delay by Plaintiffs in Bringing a Class Action Against a Public Company for Claims Under Rule 10b-5

By adopting Section 1658(b), Congress specifically sought to prevent wrongdoers from invoking the limitations period to dodge meritorious clams. *See* S. Rep. No. 146, at 9 ("Statutes of limitations are simply not proper means of deciding legitimate cases which should be decided on the merits – that is the role of the underlying substantive law."). An accrual date that can begin upon inquiry notice, before the investor has discovered that a fraud has occurred, allows the perpetrators of the fraud to use the limitations period to dismiss meritorious claims. A limitations period that begins with actual knowledge does not.

At the same time, because of the five year period of repose, use of the actual-knowledge standard does not raise concerns about the need for finality or the elimination of stale claims. Neither the risk of unfairness nor the plaintiff's lack of knowledge can be used to extend the five year period.

The residual concern seems to be a belief that the actual-knowledge standard somehow encourages inactivity by plaintiffs as a means of delaying the onset

of the limitations period.[20] Particularly in connection with class action fraud claims under Rule 10b-5, this concern is misplaced and reflects a significant misunderstanding of the practical realities of these types of actions. It also does not comport with a standard that looks to the actual knowledge of the putative class.

Investors aware of the possibility of fraud have an immediate incentive to investigate. For example, a well-hidden fraud might not be discovered until four years after the violation, requiring commencement of the action within one year to avoid being barred by the five-year statutory period of repose. *See* 28 U.S.C. § 1658(b). Investors also have an incentive to investigate to ensure that they meet the heightened pleading standards under the PSLRA. In particular, investors must plead facts demonstrating a "strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2). *See also*

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[20] *See Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1337 (7th Cir. 1997) (likening a standard that did not require investigation to the "ostrich doctrine" under criminal law and noting that: "[I]t would be highly undesirable if, suspecting securities fraud, an investor could sit back and wait out the entire three years of the repose period. . . ."). This conclusion essentially assumes that the onset of the limitations period is dependent upon the knowledge of a single investor even in the context of a putative class action. In fact, this is not the case. Given the market for securities fraud suits, a delaying plaintiff and law firm may well be bypassed by other plaintiffs or law firms that gain an advantage by becoming the first to determine the existence of the fraud and the class of putative plaintiffs. *See infra* note 21.

Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 321 (2007) (noting that the "strong inference" language raised the bar for pleading scienter). Investors who delay investigating their claims easily could find themselves without the time needed to compile the information required to meet this "strong inference" standard. *See* Lisa L. Casey, *Reforming Securities Class Actions from the Bench: Judging Fiduciaries and Fiduciary Judging*, 2003 B.Y.U. L. Rev. 1239, 1270 (because securities class actions typically are more factually and legally complex than individual litigant cases, prosecution of such claims requires greater investments of time and greater outlays of pre-trial expenses).

The possibility of deliberate inactivity also is belied by the reality of class action securities litigation. The PSLRA sought to, and did, increase the role of institutional investors – putative class representatives with the resources necessary to conduct pre-filing investigations – as plaintiffs. *See* Casey, 2003 B.Y.U. L. Rev. at 1287-89. *See also* James D. Cox, Randall S. Thomas & Lynn Bai, *There Are Plaintiffs and . . . There Are Plaintiffs: An Empirical Analysis of Securities Class Action Settlements*, 61 Vand. L. Rev. 355, 385 (2008) (finding that, in the aftermath of the PSLRA, a significant number of securities class action settlements were initiated by "institutional plaintiffs of the type desired by Congress" and that they "add substantial value to the outcome."). These institutions typically have the resources to conduct their own pre-filing investigation.

Given the role of these institutions, law firms that delay investigating the possibility of fraud may find themselves at a disadvantage.[21] Firms aware of the fraud and able to discern the applicable class will be in a position to identify possible lead plaintiffs, those investors with the largest financial interest in the relief sought. *See* 15 U.S.C. § 78u-4(a)(3)(B)(iii). The information may increase the possibility that the firms will, through private ordering, be designated as lead counsel.[22]

The appropriate legal standard also reduces the risk of plaintiff inactivity. Section 1658(b) provides that the limitations period begins upon "discovery of the facts constituting the violation" but does not specify who must make the discovery. Determination of actual knowledge in the context of class actions against public companies alleging securities fraud necessarily depends upon the information known to the class as a whole.

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[21] A significant number of law firms have the skill and expertise to bring these types of claims. *See* Securities Class Action Services Top 50 Plaintiffs Law Firms for 2008, RiskMetrics, March 2009, *posted with permission* by *RiskMetrics at University of Denver Sturm College of Law, Corporate Governance Web Site*, http://law.du.edu/documents/corporate-governance/articles-and-papers/SCAS50for2008.pdf.

[22] This "private ordering" approach to the selection of counsel is favored. *See* Chief Judge Edward R. Becker, *Third Circuit Task Force Report on Selection of Class Counsel*, 74 Temp. L. Rev. 689, 704-05 (2004). In addition, investigatory diligence by counsel can be a factor in the designation of lead counsel. *See id.* at 772.

The substance of the underlying claim presumes that members of the class are aware of the facts known to the market and, therefore, reflected in share prices. *See Basic Inc. v. Levinson*, 485 U.S. 224, 247 (1988) ("Because most publicly available information is reflected in market price, an investor's reliance on any public material misrepresentations, therefore, may be presumed for purposes of a Rule 10b-5 action."). To the extent the market is aware of the fraud, therefore, the limitations period would begin to run. Plaintiffs' inactivity or unawareness would not prevent this from occurring. This standard also provides plaintiffs with an additional incentive to immediately investigate even the possibility of fraud in order to discover what the market already knows.

IV. Under the Facts of This Case, Application of the Inquiry-Notice Standard Would Have Placed Respondents in an Untenable Position of Requiring Either Expiration of a Potentially Meritorious Claim or Filing a Claim Without Actual Knowledge of the Purported Fraud

The application of the actual-knowledge standard under the facts of this case illustrates both the wisdom of the standard and the harm that can result from the use of inquiry notice.

To meet the actual-knowledge standard for a securities fraud claim under Rule 10b-5, plaintiffs ordinarily must know of a misstatement or omission of material fact or an opinion that lacked a reasonable

basis. *See generally Basic Inc. v. Levinson*, 485 U.S. 224 (1988); *see also Virginia Bankshares v. Sandberg*, 501 U.S. 1083, 1091-94 (1991). *But see Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148 (2008) (recognizing cause of action under Rule 10b-5 on the basis of deceptive conduct).[23]

With the release of the data from the Gastrointestinal Outcomes Research study in 2000, the market was made aware of two competing, antithetical explanations for the harmful cardiovascular events incurred by those participants taking VIOXX. The data were explained either by the risk of taking VIOXX or the benefit of taking Naproxen ("Naproxen hypothesis"). The market likewise knew that both hypotheses were unproven.

The warning letter from the FDA apparently left the market's awareness unaltered. The letter asserted that certain promotional activities by Merck had resulted in incomplete disclosure. The alleged omissions, while arguably important to patients and doctors actually relying on the materials, were known to the market. If anything, the warning

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[23] For the elements of an action under Rule 10b-5, *see Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 339 (2005). In addition to a misstatement or omission of material fact, the actual-knowledge standard would require evidence of intent. *See Aaron v. SEC*, 446 U.S. 680, 695 (1980) (concluding "scienter is a necessary element of a violation of § 10(b) and Rule 10b-5.").

letter may have enhanced the credibility of the Naproxen hypothesis.[24]

Had Respondents been obligated to bring a claim under an inquiry-notice standard, before possessing evidence purporting to show that the Naproxen hypothesis was false or that Merck lacked a reasonable basis for the hypothesis, they would have confronted an untenable choice. They could either have allowed the limitations period to expire on a potentially meritorious claim or filed a fraud action based upon little more than the existence of two competing hypotheses, thereby risking dismissal.

This use of the inquiry-notice standard on the one hand permits the elimination of potentially meritorious claims and on the other hand encourages the filing of meritless claims. Meritless suits do more than waste resources. They expose plaintiffs and their counsel to the possibility of sanctions under Rule 11. Fed. R. Civ. P. 11. *See* 15 U.S.C. § 78u-4(c) (making mandatory consideration of sanctions under Rule 11 upon final adjudication of any securities fraud action).

In this case, Respondents should not have been subjected to the two year limitations period until the market had evidence purporting to show that the

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[24] The warning letter arguably placed the FDA's imprimatur on the Naproxen hypothesis by indicating that it was "a possible explanation" and, by implication, suggesting that it was reasonable.

Naproxen hypothesis was false or that Merck lacked a reasonable basis for the hypothesis. Section 1658(b) does not require more.

CONCLUSION

For these reasons, *amici* respectfully urge this Honorable Court to affirm the ruling of the United States Court of Appeals for the Third Circuit.

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In the Supreme Court of the United States

MERCK & CO., INC., ET AL., PETITIONERS

v.

RICHARD REYNOLDS, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR DR. HARLAN M. KRUMHOLZ AND DR. JOSEPH S. ROSS AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICI CURIAE

Harlan M. Krumholz, M.D., S.M., is the Harold H. Hines, Jr., Professor of Medicine and Epidemiology and Public Health at Yale University School of Medicine, where he is Director of the Robert Wood Johnson Clinical Scholars Program.[1] He is also the Director of the Yale-New Haven Hospital Center for Outcomes Research and Evaluation. He is the leading international expert in cardiovascular outcomes research, a field of investigation that involves practical research to guide clinical care and health care policy, with a particular focus on outcomes meaningful to patients and populations. Further biographical information on Dr. Krumholz is provided in Appendix A, *infra*.

Dr. Krumholz's research is specifically focused on determining optimal clinical strategies and identifying opportunities for improvement in the prevention, treatment and outcome of cardiovascular disease. Using methods of clinical epidemiology and health services research, he has sought to illuminate the balance of risks, benefits and costs of specific clinical approaches. His research efforts are intended to provide critical information to improve the quality of health care, monitor changes over time, and guide decisions about the allocation of scarce resources. Dr. Krumholz is currently leading initiatives through the

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[1] The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no counsel for a party or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus curiae or their counsel made a monetary contribution to its preparation or submission.

Centers for Medicare & Medicaid Services (CMS) to develop national outcomes measures for public reporting of hospital performance.

Dr. Krumholz is a member of the Association of American Physicians, the American Society for Clinical Investigation, and the Institute of Medicine, each of which recognizes excellence and achievement by electing for membership a small group of nationally recognized experts in medicine. He is also the author of the book *The Expert Guide to Beating Heart Disease: What You Absolutely Must Know.* He has written or co-authored more than 500 articles, reviews, and editorials in medical journals.

Joseph S. Ross, M.D., M.H.S., is an Assistant Professor in the Department of Geriatrics and Palliative Medicine at the Mount Sinai School of Medicine in New York, N.Y., and a staff physician at the James J. Peters VA Medical Center in Bronx, NY, within the HSR&D Research Enhancement Award Program. After completing his postgraduate training in primary care internal medicine, Dr. Ross was a fellow in the Robert Wood Johnson Clinical Scholars program at Yale University, earning a Masters degree in health sciences research. He was awarded a Paul B. Beeson Career Development Award in Aging Research from the National Institute on Aging in 2008. Further biographical information on Dr. Ross is provided in Appendix B, *infra*.

Using health services research methods, Dr. Ross's research focuses on examining factors which affect the use or delivery of recommended ambulatory care services for older adults and other vulnerable populations, evaluating the impact of state and fed-

eral policies on the delivery of appropriate and higher quality care, and issues related to conflicts of interest, medical professionalism, and drug safety. Dr. Ross continues to collaborate with a team of investigators under contract with the Centers for Medicare and Medicaid Services to develop statistical models that are used to measure and publicly report hospital clinical outcomes using administrative data. He has been a peer reviewer for 25 medical journals. Dr. Ross has written or co-authored 52 articles, reviews, and editorials in medical journals.

Drs. Krumholz and Ross were co-authors, along with others, of three articles on Vioxx-related issues in prominent medical journals. See *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib*, 299 J.A.M.A. 1800 (2008); *The ADVANTAGE Seeding Trial: A Review of Internal Documents*, 149 Annals of Internal Medicine 251 (2008); *What Have We Learnt From Vioxx?*, 334 B.M.J. 120 (2007). They have in the past been consultants for plaintiffs in non-securities litigation against Merck relating to Vioxx, and Dr. Krumholz has testified as an expert witness in two such cases.

Amici submit this brief in the hopes that their experience and perspectives will assist the Court in understanding the medical issues underlying this case.

SUMMARY OF ARGUMENT

Respondents in this case allege that Merck made false and misleading statements about Vioxx, a drug it marketed between 1999 and 2004. A large, double-blind clinical trial — the VIGOR study — had shown

that users of Vioxx had a higher rate of heart attacks than patients given naproxen, an older nonsteroidal anti-inflammatory drug (NSAID). There were two major possible explanations for those results — that naproxen had cardiovascular benefits (the "naproxen hypothesis"), or that Vioxx had cardiovascular risks. In an effort to alleviate concerns about Vioxx, Merck advanced the naproxen hypothesis. Respondents claim that Merck's statements advancing the napoxen hypothesis were false and misleading, because Merck itself did not believe them.

The issue before this Court concerns the standards governing whether respondents filed their securities fraud complaint not later than "2 years after the discovery of the facts constituting the violation." 28 U.S.C. 1658(b). Accordingly, this case raises the question of what a reasonable *investor* knew (or, perhaps, should have known) about the validity of the naproxen hypothesis (or the competing hypothesis that Vioxx posed cardiovascular risks) by November 6, 2001, two years before the complaint in this case was filed. This brief addresses the parallel question what a reasonable *medical professional* would have concluded about the cardiovascular benefits of naproxen — or the cardiovascular risks of Vioxx — as of that date.

Vioxx prescriptions in fact increased after the VIGOR study reported a higher rate of heart attacks in the Vioxx group in comparison with the naproxen group, and they continued to increase long after November 6, 2001. This brief focuses on four primary sources of information in the public record that might be thought to have influenced reasonable medical professionals in considering the cardiovascular safety

of Vioxx. The four sources are the VIGOR trial itself, as reported in November 2000; an analysis of VIGOR and other studies in the public record that considered the question whether Vioxx increased, or naproxen decreased, the risk of heart attacks and other adverse vascular events and was published in the *Journal of the American Medical Association* (JAMA) in August 2001; a letter sent by the FDA to Merck in September 2001 warning Merck that its promotional materials and activities for Vioxx had been false and misleading; and an article that first appeared on October 15, 2001, in the online edition of the journal *Circulation* and that considered data on cardiovascular risk from clinical trials of Vioxx that were in Merck's files but generally not available to the public.

Of the four sources, the report of the VIGOR trial raised the question whether naproxen's benefits, or Vioxx's risks, was the predominant cause of the cardiovascular results of that trial, and it advanced the naproxen hypothesis as the answer to that question. The JAMA article, which relied in large part on the VIGOR results, identified the question of the validity of the naproxen hypothesis and the possible cardiovascular risks of Vioxx as one that urgently deserved study. The FDA warning letter rebuked Merck's promotional materials for presenting the VIGOR results — and the naproxen hypothesis — in a one-sided way, but made no recommendations that prescribing patterns should change. Indeed, both sources indicated that the naproxen hypothesis was a reasonable explanation, and the JAMA article elaborated on the reasons supporting and tending to refute both it and the competing theory that Vioxx caused cardiovascular risks. In the end, because

neither source identified any new data in the public record that addressed the question of whether Vioxx conferred an increased cardiovascular risk compared with placebo, neither source would have convinced a reasonable and conscientious doctor that the naproxen hypothesis was false, or that Vioxx posed serious cardiovascular risks.

Finally, the article in *Circulation*, published online on October 15, 2001, did make new data publicly available about the risk of Vioxx compared with placebo. It presented internal and previously unavailable Merck data regarding a number of Vioxx clinical trials. The article in *Circulation* concluded that there was *no* evidence that Vioxx caused more cardiovascular events than either placebo or NSAIDs other than naproxen, and it also supported the theory that naproxen reduced the risk of cardiovascular events. To be sure, data that became public only much later made the risks of Vioxx clear. But as of November 6, 2001, the *Circulation* article provided support for the naproxen hypothesis based on new data not previously available. It would have alleviated — not strengthened — concerns that a reasonable medical professional might have had about Vioxx's cardiovascular safety as of that date.

ARGUMENT

PUBLICLY AVAILABLE INFORMATION AS OF NOVEMBER 6, 2001, WOULD NOT HAVE LED REASONABLE AND CONSCIENTIOUS DOCTORS TO DOUBT THE VALIDITY OF THE NAPROXEN HYPOTHESIS OR TO CEASE PRESCRIBING VIOXX

This securities fraud case concerns the question whether respondents, as investors, had "discover[ed]," 28 U.S.C. 1658(b), enough facts by November 6, 2001, to commence the running of the statute of limitations. The relevant facts concern whether Merck committed fraud in advancing, despite its own lack of belief, the "naproxen hypothesis" — the hypothesis that the greater number of heart attacks in patients given Vioxx as compared with patients given naproxen, another NSAID, predominantly resulted from naproxen's protective effects, rather than Vioxx's cardiovascular harms.

Although this case therefore concerns the facts about the naproxen hypothesis "discover[ed]" by an investor, the inquiry can be informed by considering the parallel *medical* question of what a reasonable medical professional would or could have known about the naproxen hypothesis as of November 6, 2001. Amici address that question by examining the most important documents that were publicly available by that date and that would have been — or that might be thought to have been — relevant to a consideration by a reasonable medical professional of the naproxen hypothesis. A reasonable medical professional examining those sources of information would

have concluded that the naproxen hypothesis as promoted by Merck was supported by evidence, and accordingly such a professional would not have had substantial concerns about the safety of Vioxx and would not have felt it necessary to cease prescribing Vioxx.

A. The VIGOR Trial And Its Report

1, On November 23, 2000, the report of the VIGOR trial was published in the *New England Journal of Medicine*. J.A. 295-318 (originally published as C. Bombardier, L. Laine, A. Reicin et al., *Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 343 N. Eng. J. Med. 1520 (2000)). The VIGOR trial was a large (8076 patients with rheumatoid arthritis) double-blind clinical trial that sought to compare the risk of upper gastrointestinal bleeding events in patients treated with Vioxx compared with those treated with naproxen, an older NSAID. From the time of Vioxx's early development, at least some scientists at Merck and consultants to Merck were concerned that Vioxx might adversely affect the ratio of prostacyclin (which promotes blood flow) and thromboxane (which promotes blood clotting), thereby upsetting the normal balance of the two substances and, potentially, increasing the risk of heart attacks or other cardiovascular events related to blood clots. Indeed, presumably for that reason, those with a history of "cerebrovascular events in two years before the study" or "myocardial infarction [*i.e.*, heart attack] or coronary bypass in the year before the study" were excluded from participation. J.A. 296.

The VIGOR publication reported the similar efficacy, or beneficial effect, of Vioxx and naproxen in treating rheumatoid arthritis, J.A. 298, 303, and it reported that Vioxx had better gastrointestinal safety than naproxen, J.A. 303-305. But it also acknowledged that "[t]he incidence of myocardial infarction was lower among patients in the naproxen group than among those in the [Vioxx] group" in the trial. J.A. 296; see J.A. 306, 310. As originally reported, the incidence of heart attacks among the Vioxx group ws 0.4 percent, while it was 0.1 percent among the naproxen group. That rate would translate to 40,000 heart attacks in a population of ten million people similar to those in the study (*i.e.*, with rheumatoid arthritis and no history of heart disease) taking Vioxx, versus 10,000 heart attacks in a similar population of ten million taking naproxen. Cf., *e.g.*, *Plaintiffs Find Payday Elusive in Vioxx Cases*, N.Y. Times, Aug. 21, 2007, at 1 (more than 20 million people in the United States took Vioxx).

The higher rate of heart attacks among the Vioxx group, which was very unlikely to have occurred by chance, could have been the result either of a harmful effect of Vioxx or a beneficial effect of naproxen (or a combination of the two). The data in the VIGOR study, as published, were unable to distinguish between the two possible explanations. Nonetheless, the report discussed in some detail and favorably the theory that naproxen is beneficial (what came to be known as the "naproxen hypothesis"), while it did not discuss the alternative theory that Vioxx was harmful.

For example, the report stated that "the effects of regular use of naproxen may be similar to [the heart-

beneficial effects] of aspirin." J.A. 310. It also noted the mechanism by which naproxen may achieve that beneficial effect, J.A. 310, and that the VIGOR "results are consistent with the theory that naproxen has a coronary protective effect." J.A. 311. The report did add that "[t]he finding that naproxen therapy was associated with a lower rate of myocardial infarction needs further confirmation in larger studies." J.A. 311. That statement itself — with its implication that there was a "finding" that naproxen had a "lower rate" of heart attacks that needed "further" confirmation in studies — strongly promoted the naproxen hypothesis. Indeed, throughout the study, naproxen is treated as the intervention variable when discussing cardiovascular risks (*e.g.*, "[t]he rate of myocardial infarction was significantly lower in the naproxen group than in the [Vioxx] group (0.1 percent vs. 0.4 percent," J.A. 310; see also J.A. 296, 306), while Vioxx was treated as the intervention variable when stating other results (*e.g.*, "The relative risk of confirmed upper gastrointestinal events was 0.4 . . . , whereas the relative risk of bleeding beyond the duodenum was 0.5." J.A. 304). That presentation, too, indicated Merck's promotion of the naproxen hypothesis as an explanation for the higher rate of heart attacks in the subjects randomized to Vioxx.

2. The results of the VIGOR study raised the question whether naproxen had cardiovascular benefits or Vioxx had cardiovascular harms. The language of the report, which was authored at least in part by Merck employees, see J.A. 313, suggested the former as the answer; its publication in the New England Journal of Medicine and its vetting by peer review

would have led readers to have confidence in that conclusion. And Vioxx sales continued to increase after the VIGOR study was published and until at least early 2004. See J.A. 55. Two features of the VIGOR study's design and reporting tended to allay fears about Vioxx and suggested to medical professionals that Vioxx was safe to prescribe.

First, a reasonable and conscientious medical professional would have been aware that Merck was in a uniquely favorable position to assess the safety of Vioxx, due to its extensive and nonpublic research on the drug. Accordingly, Merck's emphasis on, and apparent endorsement of, the naproxen hypothesis would have been accorded substantial weight by a reasonable medical professional. At that time, Merck was one of the most respected companies in the United States.[2]

Second, the VIGOR report used a defective post hoc subgroup analysis that purported to show that any increased risks of Vioxx (or benefits of naproxen) were limited to a small subgroup of the general population. In particular, the study reported results separately for (a) a small subgroup (4% of the total number of patients) with the "highest risk of myocardial infarction" for whom low-dose aspirin would be indicated, and (b) the remaining patients. J.A. 310; see

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[2] For example, in surveys conducted in 1999 and 2000 by *Fortune* magazine, Merck was ranked as the most admired pharmaceutical company in the world. *And the Winners Are . . .*, 142 Fortune (No. 7) 191-198 (Oct. 2, 2000). Earlier, *Fortune* magazine surveys named Merck as the most admired company of any sort in America for a period of seven years in a row, ending in 1993. *America's Most Admired Corporations*, 127 Fortune (No. 3) 44-53 (Feb. 8, 1993).

J.A. 306. The study thus purported to show that the increased number of heart attacks among subjects on Vioxx was entirely attributable to the higher risk aspirin-indicated subgroup, and it thereby tended to minimize any potential risk that Vioxx posed for most patients. See J.A. 310 ("The difference in the rates of myocardial infarction between the [Vioxx] and naproxen groups was not significant among the patients without indications for aspirin therapy."). That result, however, was an artifact of the study's improperly short period for counting heart attacks.[3] As a

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[3] Ordinarily, a trial's end dates should be the same for all effects being counted. The VIGOR study, however, terminated the counting of heart attacks one month before the counting of gastrointestinal events. When the editors of the *New England Journal of Medicine*, in which the VIGOR results had been published, learned that at least two of the authors of the study knew about the additional data long before its publication, they issued an "expression of concern," which explained:

> Lack of inclusion of the three events resulted in an understatement of the difference in risk of myocardial infarction between the rofecoxib and naproxen groups (presented in the article as a reduction in the risk with naproxen but shown [in an accompanying table] as an increase in the risk with rofecoxib). It also resulted in the misleading conclusion that there was a difference in the risk of myocardial infarction between the aspirin indicated and aspirin not indicated groups.

G.D. Curfman, S. Morrisey, J.M. Drazen, *Expression of Concern: Bombardier et al., "Comparison of Upper Gastrointestinal Toxicity of Refoxicob and Naproxen in Patients with Rheumatoid Arthritis," N Eng J Med 2000; 343:1520-8*, 353 N. Eng. J. Med. 2813 (2005). See also *id.* at 2814 (noting that VIGOR authors also knew of "other data on cardiovascular adverse events that we believe would have been relevant to the article" and that "[t]aken together, these inaccuracies and deletions call into question the integrity of the data on adverse cardiovascular events in [the

result, three heart attacks, all of them in the non-aspirin-indicated subgroup, were not counted. Had Merck included the three cases, the subgroup analysis would have shown an increased cardiovascular risk among Vioxx users in *both* subgroups, thus undermining the support in the subgroup analysis for the naproxen hypothesis.

B. The JAMA Article of August 2001

1. In August 22, 2001, the *Journal of the American Medical Association* (JAMA) published an article examining the risk of cardiovascular events posed by Vioxx and a similar drug, Celebrex. D. Mukherjee, S. Nissen, E. Topol, *Risk of Cardiovascular Events Associated with Selective COX-2 Inhibitors*, 286 J. Am. Med. Ass'n 954 (2001). The JAMA article noted the results of the VIGOR trial, and explained that "[t]he results of the VIGOR study can be explained by either a significant prothrombotic [*i.e.*, cardio harmful] effect from [Vioxx] or an antithrombotic [*i.e.*, cardioprotective] effect from naproxen (or conceivably both)." J.A. 326; see also J.A. 327 ("[I]t is difficult to assess whether the difference in cardiovascular event rates in VIGOR was due to a benefit from naproxen or to a prothrombotic effect from [Vioxx]."). The article also noted both an explanation for naproxen's potential benefits ("naproxen . . . resulted in a high level of platelet aggregation inhibition similar to that achieved by aspirin," J.A. 327) and an explanation for the potential cardiovascular risks of drugs like Vioxx ("Administration of selective COX-2 inhibitors [such as Vioxx] 24 hours after ischemic

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VIGOR] article").

preconditioning abolished the cardioprotective effect of late ischemic preconditioning," J.A. 328).

The article went on to discuss potential reasons to believe that Vioxx might pose a risk. The article considered a previous meta-analysis (*i.e.*, a new analysis that combines the data from several previous studies) of trials in which aspirin had been studied in comparison with placebo. The article noted that the rate of cardiovascular events in the Vioxx group in the VIGOR trial was somewhat higher than the rate in the placebo group in the aspirin-placebo trials, suggesting that Vioxx might pose greater risks than placebo. See J.A. 325. That conjecture, however, represented extremely weak evidence from which to draw any conclusions; the article cautioned that "comparison of patient populations in 2 different trials is always problematic," and that the VIGOR patients, unlike the patients in the aspirin-placebo trials, already were being treated for rheumatoid arthritis, which "increases risk of [heart attack], making intertrial comparisons difficult." J.A. 327. The article also examined the results of two smaller trials (labeled as trials 085 and 090 by Merck), which had Vioxx, namubetone (another NSAID), and placebo arms. J.A. 324. Those studies together "did not demonstrate the significant increase in cardiovascular event rate noted in VIGOR," and in that respect they tended to support the naproxen hypothesis. J.A. 329. But their results were of very limited value because they "had smaller sample sizes, used only 25% of the dose of [Vioxx] used in VIGOR, and had few events for meaningful comparison." J.A. 329.

The article noted that "it is useful to consider" that COX-2 inhibitors such as Vioxx may "show less

propensity for gastrointestinal toxicity but greater prothrombotic potential," while aspirin and naproxen have the reverse effects. J.A. 330. But the article noted several "significant limitations" on its analysis. J.A. 330. The authors speculated that their "findings *suggest* a *potential* increase in cardiovascular event rates for the presently available COX-2 inhibitors," and "urge[d] caution in prescribing these agents to patients at risk for cardiovascular morbidity" until "a randomized clinical trial" could be conducted. J.A. 331 (emphasis added). But they noted as well the reverse potential: that cardiovascular conditions have an "inflammatory component" that "may be suppressible by COX-2 inhibitors" such as Vioxx. J.A. 331. While they urged "caution" in prescribing Vioxx for patients at risk — wise advice for any physician in prescribing drugs that could have adverse effects — they did not recommend the drug be suspended or severely limited even for at-risk patients pending a trial that could provide a definitive answer. The article concluded that "[g]iven the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents." J.A. 331.

2. The JAMA article, while giving a useful overview of the state of knowledge from publicly available sources, provided no new information that would cause a reasonable medical professional to reject the naproxen hypothesis. Most of the data used in the article had already been published.[4] While the JAMA

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[4] The two smaller studies considered in the JAMA article (numbers 085 and 090) had not yet been published, further em-

article continued to pose the question whether Vioxx had cardiovascular risks, or naproxen instead had beneficial cardiovascular effects, its conclusion was only that further study was necessary. The authors of the article were very well-known researchers who themselves perform studies, and their perspectives on the need for further research were credible. But, given the limitations on the data that were publicly available regarding the cardiovascular effects of Vioxx, they were unable to advance the state of knowledge. Reasonable medical professionals would not have altered — and did not alter — their views of Vioxx and its potential risks as a result of the article, as indicated by Vioxx's increasing sales.

C. The FDA Warning Letter

On September 17, 2001, the FDA's Division of Drug Marketing, Advertising and Communication sent Merck a warning letter regarding "promotional activities and materials for the marketing of Vioxx." J.A. 339. The letter stated that Merck's "promotional activities and materials" were "false, lacking in fair balance, or otherwise misleading." J.A. 339. Much of the warning had to do with Merck's promotional activities regarding matters other than Vioxx's car-

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phasizing the preliminary nature of any reported results. They had not yet undergone peer review. To give perspective on how little information was available from those studies, the number of adverse events in the Vioxx group in 085 was 1 and in 090 was 6. And their very short duration (085 lasted only six weeks, J.A. 324) also limited the value of their data for these purposes. As noted above, the JAMA article itself concluded that those studies, though they tended to support the naproxen hypothesis, were of very limited value.

diovascular effects. See J.A. 340 ("minimize the Vioxx/Coumadin (warfarin) drug interaction, omit important risk information, make unsubstantiated superiority claims against other NSAIDs, and promote Vioxx for unapproved uses"); see J.A. 346-351.

The FDA letter did address the fact that the "promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarctions" compared with patients on naproxen. J.A. 340. The letter did not, however, add any new information regarding the safety of Vioxx or call for changes in prescribing patterns. Instead, it merely recognized the continued uncertainty. It noted that "the exact reason for the increased rate of [heart attacks] observed in the Vioxx treatment group is unknown," and that the hypothesis that naproxen had cardiovascular benefits "is a possible explanation." J.A. 340 (emphasis added). The FDA's complaint was that the promotional materials "fail[ed] to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that Vioxx may have pro-thrombotic properties." J.A. 340; see also J.A. 342 ("Although . . . the reason for these differences is not clear, possible explanations include both an ability of naproxen to function as a cardioprotective agent and a pro-thrombotic property of Vioxx.").

The FDA letter detailed specific audio conferences and other promotional activities in which Merck had understated the rate of cardiovascular events suffered by the Vioxx patients in the VIGOR study and had advanced the naproxen hypothesis without not-

ing that it was unproven and that there remained the possibility that Vioxx caused cardiovascular risks. See J.A. 343-344, 345-346. Because "the situation is not at all clear" and "the reason for the difference between Vioxx and naproxen has not been determined," Merck's promotional materials endorsing the naproxen hypothesis without a balanced treatment were misleading. J.A. 344.[5]

The FDA letter thus continued to rely on the scientific findings already in the public record. It rebuked Merck for understating the potentially unfavorable VIGOR results and failing to present the naproxen hypothesis in a sufficiently balanced manner. The letter would have suggested to medical professionals who had been misled by Merck's promotional campaign that the naproxen hypothesis was unproven and that other explanations for the VIGOR results remained possible. The letter did not, however, add anything to public knowledge about the risks posed by Vioxx, and it made quite clear that the naproxen hypothesis retained credibility and, indeed, could even be used in promotional materials, so long as it was presented in a sufficiently balanced way. Nothing in the FDA letter suggested that the naproxen hypothesis was not *more* likely than the competing view that Vioxx posed cardiovascular risks. The letter did not warn doctors about Vioxx or

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[5] The FDA letter did correct the error regarding the underreporting of cardiovascular events in the VIGOR trial and the consequent mistaken claim about the aspirin subgroup. J.A. 345; see note 3, *supra*. While this did remove one support for the naproxen hypothesis, it did not in any way suggest that the competing theory that Vioxx posed cardiovascular risks was correct.

suggest that prescribing patterns should change. The letter would not have caused reasonable medical professionals to conclude that Vioxx in fact posed serious cardiovascular risks or that treatment with Vioxx should be discontinued.

D. The Review of Merck Data Published In *Circulation*

1. The journal *Circulation*, the flagship journal of the American Heart Association, published an article on the cardiovascular safety of Vioxx on October 15, 2001 online (and in print a few weeks later). M.A. Konstam, M.R. Weir, A. Reicin et al., *Cardiovascular Thrombotic Events in Controlled, Clinical Trials of Rofecoxib,* 104 Circulation 2280 (2001). The two leading authors, Drs. Konstam and Weir, had been consultants to Merck, though Merck did not pay them for the article. *Id.* at 2280. Dr. Konstam in particular was Chief of Cardiology at the New England Medical Center and a respected academic leader in the field. The other five co-authors were Merck employees. *Ibid.*

While the article did not itself result from any new clinical trials, it did add to the publicly available medical data about Vioxx, because it considered 23 trials from Merck's internal files that had compared Vioxx to placebo, naproxen, or another nonselective NSAID such as ibuprofen. Most of those trials had not previously been published, and the cardiovascular event data from those trials that had been published had not previously been available to the public.

The comparison of Vioxx with placebo, on which the *Circulation* study added new data, was at the

heart of the controversy. The definitive resolution of the validity of the naproxen hypothesis turned squarely on whether Vioxx, in comparison to placebo, would be associated with cardiovascular risks or would be neutral. If patients given Vioxx and placebo suffered the same level of cardiovascular risks, then the VIGOR findings would likely have turned on the beneficial effects of naproxen — *i.e.*, the naproxen hypothesis would be correct. But if patients given Vioxx suffered more cardiac events in comparison with those given placebo, then the naproxen hypothesis put forward by Merck would be mistaken as a full explanation for the differences observed in the VIGOR study.

2. The article explained that "[t]he primary objective of this analysis was to assess whether [Vioxx] was associated with an excess of [cardiovascular] events," 104 Circulation at 2285 — *i.e.*, the validity of the naproxen hypothesis. The analysis counted cardiovascular events according to what is termed "APTC [Antiplatelet Trialists' Collaboration] standards," which comprise cardiovascular, hemorrhagic, and unknown deaths; nonfatal heart attacks; and nonfatal strokes. *Id.* at 2283. The conclusions of the analysis with respect to the safety of Vioxx were clear: "Most importantly, the results of the [Vioxx] relative to placebo comparison demonstrated a comparable risk of APTC events in both groups," a conclusion that "*[is] most reassuring that there is no evidence for any increased risk of [cardiovascular] thrombotic events with [Vioxx].*" *Id.* at 2285 (emphasis added). The article repeated substantially the same "no evidence" statement twice more. *Id.* at 2280, 2287.

The article's conclusions about naproxen's benefits were only slightly more guarded. The article endorsed the naproxen hypothesis. "The available data indicate that naproxen was different than other NSAIDs and was associated with decreased risk of [cardiovascular] events relative to [Vioxx]." *Id.* at 2285; see *id.* at 2280 ("Differences observed [in the VIGOR study] between [Vioxx] and naproxen are likely the result of the antiplatelet effects of the latter agent."). But the article did, more cautiously, add that "[a]lthough the data are suggestive, neither the VIGOR results nor the current analysis provide sufficient evidence to establish the cardioprotective benefits of naproxen." *Id.* at 2286.

3. The *Circulation* article added to the evidence available to medical professionals on the validity of the naproxen hypothesis, because it was based on data from Merck's files that was previously available only to Merck. Its results unequivocally provided substantial support to Merck's claim that Vioxx did not pose cardiovascular risks, and its results added substantially to the support for the naproxen hypothesis.

Later evidence that became public in 2003-2004 revealed that Vioxx in fact posed serious risks and that the naproxen hypothesis was mistaken. See Resp. Br. 9-10, J.A. 164-165, 174-175, 180. Indeed, Merck withdrew Vioxx from the market in 2004 after an interim analysis of a large randomized trial that studied the impact of Vioxx on reducing risk of colon polyp recurrence, known as the APPROVe trial, revealed that Vioxx in fact increased risk of cardiovascular risk when compared with placebo. J.A. 183-185. But the defects that existed in the *Circulation*

article would not have been apparent in November 2001.[6] As of November 6, 2001, a reasonable medical professional would have concluded that the naproxen hypothesis was likely correct, and that Vioxx did not pose cardiovascular risks sufficient to warrant reducing or ceasing using it to treat indicated conditions.[7]

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[6] One important defect was the authors' use of the APTC standards to identify cardiovascular risk. The APTC standards are appropriate, as the name suggests, for the purpose of testing the net benefit, considering efficacy and safety, of antiplatelet medications. They were not, however, designed for use in measuring the cardiovascular risks of drugs. A better measure would include all nonfatal cardiovascular adverse events (not merely nonfatal heart attacks and nonfatal strokes). It would also include deaths from *all* causes, because cardiovascular deaths are not always identified accurately, especially in clinical trials that were not designed (as the trials examined in the *Circulation* article were not) to examine cardiovascular outcomes. For example, death resulting from a car accident may in fact be caused by a heart attack that triggered the accident, but, especially if the person doing the classification is not specifically alerted to that possibility, the car accident may simply be identified as the cause of death. That is particularly true with Alzheimer's patients, who constituted two of the trials examined and about 25% of the total patients given Vioxx or placebo in Vioxx-placebo trials. See 104 Circulation at 2283 (Table 3). Given their cognitive impairments, Alzheimer's patients may not report symptoms accurately and may not be as thoroughly evaluated when brought for medical attention. It is thus particularly likely that deaths due to cardiovascular events would not be accurately reported in such patients.

[7] Amici, along with several colleagues, have themselves investigated the question of when the greater cardiovascular risk of Vioxx in comparison with placebo could have been known, and their research will be the subject of a forthcoming article in a prominent medical journal to be published prior to November 30, 2009. Due to prepublication embargo restrictions imposed by the journal, amici are unable at this time to provide any further information regarding their forthcoming study.

CONCLUSION

Materials in the public record by November 6, 2001, were insufficient to put a reasonable medical professional on notice that the naproxen hypothesis was flawed.

Respectfully submitted.

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APPENDIX

Appendix A

Harlan M. Krumholz, MD, SM

Selected Awards and Honors:

1992	Finalist, American Heart Association Young Investigator Award
1996	William Harvey Award for Medical Journalism
1996-1999	Paul Beeson Faculty Scholar
1996-	Fellow, American College of Cardiology
1996-	Fellow, American Heart Association Council on Clinical Cardiology
1999-	Fellow, American College of Physicians-American Society of Internal Medicine
2000	William Coleman Branton Lecture, Mid America Heart Institute
2000-	Elected, American Society for Clinical Investigation
2003	Best Doctors in America
2004-	Elected, Association of American Physicians
2007	Award of Meritorious Achievement, American Heart Association
2007-	Elected, Institute of Medicine of the National Academies of Science
2008-	Elected, Connecticut Academy of Science and Engineering

Selected Recent National Committees:

2004	Scientific Advisory and Coordinating Committee, American Heart Association
2004	Outcomes: Impact from Observational Studies Writing Group from the Dispari-

	ties Conference, American Heart Association
2004	Expert Panel, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention
2004-2006	Standards for Statistical Models Used for Public Reporting of Outcomes Writing Group, American Heart Association
2005	Case Study Development Group of the Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation, Institute of Medicine
2005-2006	Co-Chair, Quality in Cardiovascular Imaging Working Group, American College of Cardiology
2005-2006	Advisory Panel, Gender Differences in Cardiovascular Care Feasibility Study, National Committee for Quality Assurance
2005-2006	Co-Chair, Heart IT Taskforce, American Heart Association
2005-2006	Research Advisory Council, National Committee for Quality Assurance
2005-2008	Acute Coronary Syndromes/Coronary Artery Disease Clinical Data Standards Writing Committee, American College of Cardiology/American Heart Association
2005-	Chair, Cardiac Scientific Advisory Board, UnitedHealthcare
2005-	Quality Strategic Directions Committee, American College of Cardiology

2005-	Chair, Standardizing Ambulatory Care Performance Measures Composite Measures Technical Advisory Panel, National Quality Forum
2005-	Acute Coronary Syndromes Registry Workgroup, American College of Cardiology
2006	Heart Failure and Hypertrophy Working Group, National Heart, Lung, and Blood Institute
2006-2008	Task Force on Practice Guidelines, American College of Cardiology/American Heart Association
2006-2008	Chair, D2B Quality Alliance Steering Committee, American College of Cardiology
2006-	Acute Coronary Syndrome Collaborative Workgroup, American College of Cardiology
2007	Review Panel, 2007 Rippel Scholars Award, Fannie E. Rippel Foundation
2007-	Task Force Reviewer, Guideline for the Management of Patients with Stable Ischemic Heart Disease (SIHD), American College of Cardiology/American Heart Association
2007-	Board of Directors, WikiDoc Foundation
2007-	Liaison to the Peer Review Working Group of the Advisory Committee to the Director, National Institutes of Health
2007-	Advisory Panel to the Cardiovascular Diseases Expert Working Group of the Global Burden of Disease Study, Centers for Disease Control and Prevention

2007-	Blue Ribbon Task Force on Health System Reform, American College of Cardiology
2008-	Clinical Advisory Group, VHA, Inc.
2008-	Methodology for the Selection and Creation of Performance Measures for Quantifying the Quality of Cardiovascular Care Writing Committee, American College of Cardiology/American Heart Association
2008-	Expert Panel on Integrated CVD Risk Reduction in Adults and the Guidelines Implementation Work Group, National Heart, Lung, and Blood Institute
2008-	Committee on Human Rights correspondent, National Academy of Sciences, National Academy of Engineering, and the Institute of Medicine
2008-	Chair, Quality Programs and Products Subcommittee of the Clinical Quality Committee, American College of Cardiology
2009	Science Classification Task Force, American Heart Association
2009-	Scientific Advisory Group, Institute for Healthcare Improvement
2009-	Chair, Steering Committee of the Hospital to Home (H2H) Initiative, American College of Cardiology
2009-	Board of Trustees, American College of Cardiology

Editorial Boards:

1996-1999	Journal Watch: Women's Health (Associate Editor)

1996-2000	Journal Watch for Cardiology (Associate Editor)
1997	American Journal of Medicine
1999-2003	Journal of the American College of Cardiology
2000-2005	American Heart Journal
2000-	Congestive Heart Failure
2000-	Journal Watch for Cardiology (Editor-in-Chief)
2002	Critical Pathways in Cardiology
2003-	Circulation (Associate Editor)
2003-	American Journal of Managed Care
2003-	Journal of Cardiovascular Medicine, formerly theItalian Heart Journal (International Scientific Board)
2005-	Central European Journal of Medicine
2006-	Current Cardiovascular Risk Reports
2007-	Archives of Medical Science
2007-	JACC: Cardiovascular Imaging (Senior Consulting Editor)
2008-	Circulation: Cardiovascular Quality and Outcomes (Editor)

APPENDIX B

Joseph S. Ross, M.D., M.H.S.

Awards and Honors:

2004-2006	Robert Wood Johnson Clinical Scholars Award
2006	National Institute on Aging Summer Institute Participant
2006	Distinguished Reviewer, Journal of General Internal Medicine
2006-2008	John A. Hartford Center of Excellence Scholar
2008	Exceptional Reviewer, Medical Care
2008	American Heart Association Quality of Care and Outcomes Research Young Investigator Award
2008-2013	Paul B. Beeson Career Development Award in Aging Research
2009	Exceptional Reviewer, Medical Care
2009	Dr. Solomon Silver Award in Clinical Medicine for advances in patient-oriented research, established by the Richard and Hinda Rosenthal Foundation

National Committees:

2007-	Department of Veteran Affairs, Stroke Quality Enhancement Research Initiative (QUERI), Workgroup 3: Stroke Risk Factor Management
2009-	Society of General Internal Medicine, Health Policy Committee, Research Subcommittee

Editorial Boards:

2008-	Journal of General Internal Medicine (Role: Advisory)
2009-	PLoS ONE (Role: Academic Editor)

Peer Reviewer (Journals):

African Health Sciences
American Heart Journal
American Journal of Managed Care
Archives of General Psychiatry
Archives of Internal Medicine
Arthritis Care and Research
Breast Cancer: Basic and Clinical Research (Open Access)
Circulation
Circulation: Cardiovascular Quality and Outcomes
Diabetes Research and Clinical Practice
Health and Quality of Life Outcomes
Health Affairs
Health Policy
Health Services Research
JAMA
Journal of General Internal Medicine
Journal of Gerontology: Medical Sciences
Journal of Palliative Medicine
Journal of Rural Health
Journal of Urology
Journal of Women's Health
Medical Care
Personalized Medicine
PLoS Medicine
PLoS ONE

AMICUS CURIAE BRIEF

SUPREME COURT, U.S.
OCT 26 2009

No. 08-905

IN THE

Supreme Court of the United States

MERCK & CO., INC., *et al.*,

Petitioners,

v.

RICHARD REYNOLDS, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF AMICUS CURIAE THE NATIONAL ASSOCIATION OF SHAREHOLDER AND CONSUMER ATTORNEYS IN SUPPORT OF RESPONDENTS

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Stephen J. Choi, Jill E. Fisch & A.C. Pritchard, *Do Institutions Matter? The Impact of the Lead Plaintiff Provision of the Private Securities Litigation Reform Act*, 83 WASH. U.L.Q. 869 (2005) 9

Todd Foster, Ronald I. Miller, Ph.D. and Stephanie Plancich, Ph.D., *Recent Trends in Shareholder Class Action Litigation: Filings Plummet, Settlements Soar*, NERA Economic Consulting Study (Jan. 2007), www.nera.com/publication.asp?P_ID=3028 9

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INTEREST OF *AMICUS CURIAE* [1]

The National Association of Shareholder and Consumer Attorneys ("NASCAT") is a nonprofit membership organization founded in 1988. NASCAT's member law firms represent investors (both institutions as well as individuals) in securities fraud and shareholder derivative cases throughout the United States. NASCAT and its members are dedicated to representing victims of fraudulent schemes, and so-called "white collar" criminal activity in cases that have the potential for advancing the state of the law, educating the public, modifying corporate behavior, and providing compensation and access to justice for the wrongs inflicted upon victims. NASCAT advocates the principled interpretation and application of the federal securities laws – including the Securities Exchange Act of 1934 ("Exchange Act"), the Securities Act of 1933 ("Securities Act"), and the Private Securities Litigation Reform Act of 1995 ("PSLRA") – in order to protect investors from manipulative, deceptive and fraudulent practices, and to ensure that this nation's capital markets operate fairly and efficiently. Together with other public interest groups, NASCAT has previously filed *amicus curiae* briefs in this Court in cases involving

1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae*, or their counsel made a monetary contribution to its preparation or submission. The parties have filed blanket consents with respect to the filing of this brief.

the construction and application of the federal securities laws.[2]

INTRODUCTION

This action concerns the correct construction and interpretation of 28 U.S.C. § 1658(b), the statute of limitations provision that applies to securities fraud actions brought under the Exchange Act. This provision states that "a private right of action that involves a claim of fraud, deceit, manipulation, or contrivance in contravention of a regulatory requirement . . . may be brought not later than the earlier of . . . 2 years after the discovery of the facts constituting the violation; or . . . 5 years after such violation." Congress adopted 28 U.S.C. §1658(b) as part of the Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, § 804, 116 Stat. 801 ("Sarbanes-Oxley"), in response to this Court's decision in *Lampf, Pleva, Lipkind, Prupis & Petigrow* v. *Gilbertson*, 501 U.S. 350 (1991). In *Lampf*, the Court held that securities fraud claims were governed by a uniform federal limitations period and must be brought within the earlier of one year "after discovery of the facts constituting the violation" or three years after such

---

2. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007) (NCPERS-NASCAT); *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71 (2006) (NASCAT-AARP); *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005) (AARP-NASCAT-Consumer Federation of America); *S.E.C. v. Zandford*, 535 U.S. 813 (2002) (AARP-NASCAT); *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164 (1994) (NASCAT); *Musick, Peeler & Garrett v. Employers Inc. of Wausau*, 508 U.S. 286 (1993) (NASCAT).

violation. *Id.* at 363. While Congress, in 2002, extended the relevant periods of limitation and repose to two years and five years respectively, it retained *Lampf's* trigger for the limitations period to begin running upon "discovery of the facts constituting the violation." 28 U.S.C. § 1658(b). Securities fraud claims may be based on material misstatements of facts or misstatements of "reasons, opinion, or belief." *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1090 (1991).

Securities fraud is often difficult to uncover and securities fraud cases are typically complex. Justice Kennedy highlighted this issue in *Lampf*:

> The real burden on most investors, however, is the initial matter of discovering whether a violation of the securities laws occurred at all. This is particularly the case for victims of the classic fraudlike case that often arises under § 10(b). . . The most extensive and corrupt schemes may not be discovered within the time allowed for bringing an express cause of action under the 1934 Act.

Lampf, 501 U.S. at 377 (Kennedy, J., dissenting); *see also* S. Rep. No. 104-98, at 42 (1995), *reprinted in* 1995 U.S.C.C.A.N. 679, 726 (discussing the statute of limitations provision of the Exchange Act and stating "[e]vents only come to light years after the original distribution of securities and the Lampf cases could well mean that by the time investors discover they have a case, they are already barred from the courthouse").

Nonetheless, Petitioners and their *amici* suggest that the statute of limitations contained in 28 U.S.C. § 1658(b) – which Congress enacted to give plaintiffs ***more*** time to bring suit – should now be interpreted so as to provide ***less*** time for plaintiffs to bring viable securities fraud suits.

ARGUMENT

I. The Statute Of Limitations Provision Should Be Interpreted With An Understanding Of The Critical Role Played By Private Securities Litigation To Combating Securities Fraud

This Court has acknowledged on numerous occasions the importance of the private right of action for securities fraud as a supplement to government enforcement. *See, e.g., Tellabs*, 551 U.S. at 313 (private actions are an "essential supplement to criminal prosecutions and civil enforcement actions brought, respectively, by the Department of Justice and the Securities and Exchange Commission"); *Dura*, 544 U.S. at 345 ("the availability of private securities fraud actions" acts to deter fraud and thereby helps maintain "public confidence in the [securities] marketplace"); *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988) (private right of action "constitutes an essential tool for enforcement of the 1934 Act's requirements") (citations omitted); *Randall v. Loftsgaarden*, 478 U.S. 647, 664 (1986) (noting "the deterrent value of private rights of action" under the securities laws); *Bateman Eichler, Hill Richards, Inc. v. Berner*, 472 U.S. 299, 310 (1985) ("implied private actions provide 'a most effective weapon in the enforcement' of the securities laws and

are 'a necessary supplement to [SEC] action'") (quoting *J.I. Case Co. v. Borak*, 377 U.S. 426, 432 (1964)); *Herman & MacLean v. Huddleston*, 459 U.S. 375, 390 (1983) ("the interests of plaintiffs in [private securities fraud cases] are significant [and since] [d]efrauded investors are among the very individuals Congress sought to protect in the securities laws[,] [i]f they prove that it is more likely than not that they were defrauded, they should recover.")

The SEC has also acknowledged the importance of private securities litigation. In Congressional testimony, former SEC Chairman Arthur Levitt stated, "Private actions are crucial to the integrity of our disclosure system because they provide a direct incentive for issuers and other market participants to meet their obligations under the securities laws." S. Rep. No. 104-98, at 38 (1995), *reprinted in* 1995 U.S.C.C.A.N. 679, 716. Similarly, in 1991 then Chairman Richard Breeden testified before the Banking Committee that private securities actions were an "essential tool in the enforcement of the federal securities laws. Because the Commission does not have adequate resources to detect and prosecute all violations of the federal securities laws, private actions perform a critical role in preserving the integrity of our securities markets." *Id.* at 37; 1995 U.S.C.C.A.N. at 716.

Private securities actions are also necessary to ensure that meaningful recovery is provided to victims of securities fraud. Private actions routinely recover significantly more money for distribution to shareholders than comparable SEC settlements. For example, the securities class action against Enron Corp., which settled

in 2007 for an aggregate amount of more than $7.2 billion, was the largest securities class action settlement since the passage of the PSLRA; in fact, it represented the largest settlement in class action history. *See* Coughlin Stoia Geller Rudman & Robbins LLP, *Securities Fraud* (2009), http://www.csgrr.com/csgrr-cgi-bin/mil?templ=firm/practice-areas-sec.html. By contrast, the SEC's Enron-related settlement fund held only approximately $440 million as of February 2007. *See* U.S. Securities and Exchange Commission, *Enron* (May 14, 2007), http://www.sec.gov/divisions/enforce/claims/enron.htm. Likewise, in the *WorldCom* litigation, the SEC obtained $750 million for investors, while the related securities class action obtained approximately $6.1 billion for investors. *Compare* U.S. Securities and Exchange Commission, *The Honorable Jed Rakoff Approves Settlement of SEC's Claim for a Civil Penalty Against Worldcom* (July 7, 2003), http://www.sec.gov/news/press/2003-81.htm (SEC press release discussing approval of the WorldCom settlement for $750 million in cash and stock), *with* Barrack, Rodos & Bacine, *Case Study: Worldcom* (2009), http://www.barrack.com/Case-Study-Worldcom-3910.html (discussing private settlement in WorldCom securities class action for more than $6.13 billion). The *Dynegy* case provides another example. The private securities class action recovered in excess of $474 million for shareholders while the SEC settled its related Dynegy case for only $3 million. *Compare* University of California, *Federal Court Approves Dynegy Securities Fraud Settlement* (July 8, 2005), http://www.universityofcalifornia.edu/news/article/10110, *with* U.S. Securities and Exchange Commission, *Dynegy Settles Securities Fraud Charges Involving SPEs, Round-Trip Energy Trades* (Sept. 24, 2002), http://www.sec.gov/news/press/2002-140.htm.

Nonetheless, certain of Petitioners' *amici* assert that securities class actions are meritless, abusive and encourage forced settlements which ultimately reduce shareholder value. *See* Brief for Chamber of Commerce of the U.S. as Amicus Curiae Supporting Petitioners at 30-32, *Merck & Co., Inc., et al., v. Richard Reynolds, et al.*, No. 08-905; Brief for The Pharmaceutical and Research Manufacturers of America as Amicus Curiae Supporting Petitioners, at 5-6, *Merck & Co., Inc., et al., v. Richard Reynolds, et al.*, No. 08-905. Not only are these assertions belied by the oft-repeated statements of this Court and the SEC, such massive and infamous securities frauds as those perpetrated by Bernard Madoff, Alan Stanford, and numerous other companies and individuals show that the need for private enforcement of the securities laws is as great as ever.

II. A Restrictive Interpretation Of The Statute Of Limitations Is Inconsistent With Congressional Intent

Petitioners also ignore the fact that Congress has already enacted legislative measures to protect companies from abusive, frivolous actions. Congress (via the PSLRA) has heightened the pleading standards applicable to securities fraud actions, prohibited abusive practices, including the payment of bounties to named plaintiffs, encourages defendants to fight abusive claims, and sought to increase participation by large institutional investors. *See, e.g.*, 15 U.S.C. § 78u-4(a)(2)(A)(vi); 15 U.S.C. § 78u-4(b)(1)(B); 15 U.S.C. § 78u-4(b)(2).[3] The PSLRA also imposed a mandatory

3. The heightened pleading standard requires a complainant to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2).

discovery stay until the complaint survives a motion to dismiss. 15 U.S.C. § 78u-4(b)(3)(B). The discovery stay is intended to prevent perceived pre-PSLRA abusive discovery tactics by directing district courts to first determine the legal sufficiency of the claims in securities fraud class actions before permitting any discovery to be served. *See Lander v. Hartford Life & Annuity Ins. Co.*, 251 F.3d 101, 107 (2d Cir. 2001). Thus, this provision of the PSLRA creates a powerful incentive not to file flimsy complaints in an effort to force settlements by defendants.[4]

The PSLRA is achieving its goal of eliminating frivolous litigation.[5] For example, dismissal rates of securities class actions have risen measurably since the passage of the PSLRA. Between 1991 and 1995, dismissals accounted for just under 20% of dispositions

4. Nevertheless, interpreting the statute of limitations in the way Petitioners and their *amici* suggest would frustrate the goal of the PSLRA to eliminate frivolous lawsuits by actually encouraging plaintiffs to file complaints early in an attempt to avoid the running of the statute of limitations.

5. It is recognized that while the PSLRA was intended to eliminate frivolous litigation, it was not intended to eliminate meritorious securities fraud complaints. *See, e.g., Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1235 (9th Cir. 2004) ("The PSLRA was designed to eliminate frivolous actions, but not actions of substance."); *ABC Arbitrage Plaintiffs Group v. Tchuruk*, 291 F.3d 336, 354 (5th Cir. 2002) ("[The PSLRA] was not enacted to raise the pleading burdens under Rule 9(b) and section 78u-4(b)(1) to such a level that facially valid claims must be routinely dismissed on Rule 9(b) and 12(b)(6) motions . . . [T]he PSLRA may have changed federal securities law; it did not eliminate it") (citations omitted).

of securities fraud class actions. *See* Todd Foster, Ronald I. Miller, Ph.D. and Stephanie Plancich, Ph.D., *Recent Trends in Shareholder Class Action Litigation: Filings Plummet, Settlements Soar*, NERA Economic Consulting Study (Jan. 2007), at 4 (available at www.nera.com/publication.asp?P_ID=3028). However, between 2000 and 2004, that rate increased to 38.2%. *See id*; *see also* Stephen J. Choi and Robert B. Thompson, *Securities Litigation and Its Lawyers: Changes After the First Decade After the PSLRA*, 106 COLUM. L. REV. 1489, 1501 (2006) (citing a report indicating that the PSLRA has discouraged filing frivolous actions but not meritorious ones against companies with highly volatile stocks).[6] The PSLRA's goal of increased participation by institutional investors has also been accomplished. *See* Stephen J. Choi, Jill E. Fisch & A.C. Pritchard, *Do Institutions Matter? The Impact of the Lead Plaintiff Provision of the Private Securities Litigation Reform Act*, 83 WASH. U.L.Q. 869, 879 (2005) (discussing the fact that public pension funds

6. The Brief for the Chamber of Commerce notes that despite these efforts by Congress to reign in abusive securities litigation, the number of securities class action filings is actually rising. *See* Brief for Chamber of Commerce of the U.S. as Amicus Curiae Supporting Petitioners at 32, *Merck & Co., Inc., et al., v. Richard Reynolds, et al.*, No. 08-905. However, what this brief fails to take into consideration is that the driver for the increased filings, particularly in 2008, has been the recent number of frauds related to the collapse of numerous financial institutions which accumulated undisclosed billions in ultra-risky securities including subprime debt. *See* Stephanie Plancich & Svetlana Starykh, *2008 Trends in Securities Class Actions*, NERA Economic Consulting (Dec. 2008), at 1 (available at www.nera.com/publication.asp?P_ID=3674). Thus, this increase in filings should be viewed as an unusual event.

in particular have become more active in securities class action litigation as a result of the PSLRA).

One action that Congress did ***not*** take in trying to cut down on abusive Section 10(b) litigation was to truncate the statute of limitations applicable to such actions. That is because the statute of limitations does not go to the merits of such actions, but rather addresses only their timeliness. Congress was presumably well aware that defendants have frequently moved to dismiss on the grounds of statute of limitations, including in cases involving some of the most egregious of frauds. *See, e.g., In re Tyco Int'l Ltd.*, No. MDL 02-1335-B, 02-266-B, 2004 WL 2348315, at *18 (D.N.H. Oct. 14, 2004); *In re AOL Time Warner, Inc., Sec. & ERISA Litig.*, 381 F. Supp. 2d 192, 210 (S.D.N.Y. 2004); *In re Enron Corp. Sec. Litig.*, No. MDL-1446, 2004 WL 764664, at *1 (S.D. Tex. Mar. 31, 2004).

Indeed, not only did Congress not truncate the statute of limitations for securities actions, it ***expanded*** the statute of limitations for such actions. In so doing, it appears that Congress was specifically aware of the additional and unprecedented pleading burdens that it had imposed on securities fraud plaintiffs when it passed the PSLRA seven years earlier in 1995, and decided to lengthen the statute of limitations to give plaintiffs – who had already discovered a violation – additional time to develop the particularized facts needed to plead a strong inference of scienter as to each possible defendant. *See* S. Rep. 107-146, at 9 (2002) (discussing one year statute of limitations being unfair "when considered in light of the significant obstacles that current law places between a victim and the courthouse

in securities fraud cases."). Petitioners' proposed rule is therefore irreconcilable not only with the plain text of the statute, but with the statute's legislative history. Congress surely did not intend for its expansion of the limitations period to benefit the Bernard Madoffs of the world at the expense of victims of such fraud – particularly when Congress had the opportunity to adopt a more traditional "accrual rule" and instead expressly enacted a "discovery rule."

Moreover, Courts have expressly recognized that a restrictive interpretation of the statute of limitations would frustrate Congress' intent in enacting the PSLRA by leading to more "premature and groundless suits." *Law v. Medco Research, Inc.*, 113 F.3d 781, 786 (7th Cir. 1997); *see also Mathews v. Kidder Peabody & Co., Inc.*, 260 F.3d 239, 253 (3d Cir. 2001) (stating that too broad an interpretation of the statute of limitations would lead to a "flood of untimely litigation"); *Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997) (stating that the statute of limitations provision "must not be construed so broadly that the statute of limitations starts running too soon for the victim of the fraud to be able to bring suit."). Instead, before the statute of limitations begins to run, "[t]he facts . . . must be sufficiently probative of fraud — sufficiently advanced beyond the stage of a mere suspicion, sufficiently confirmed or substantiated." *Fujisawa Pharm. Co.*, 115 F.3d at 1335.

III. In Most Instances, Statute Of Limitations Questions Based On A Retrospective Constructive Discovery Analysis Should Be Reserved For Juries

As courts have recognized, the question of whether constructive discovery of the facts constituting the violation should be imputed to a plaintiff is a fact-intensive inquiry that typically is for a jury to decide. *See e.g.*, *Tello v. Dean Witter Reynolds, Inc.*, 410 F.3d 1275, 1284 (11th Cir. 2005) ("The determination of ***when*** inquiry notice occurred . . . [is] necessarily fact-specific to each case. Accordingly . . . [this issue is] particularly suited for a jury's consideration.") (internal citations and quotations omitted); *Young v. Lepone*, 305 F.3d 1, 9 (1st Cir. 2002) ("The multifaceted question of whether storm warnings were apparent involves issues of fact. In the archetypical case, therefore, it is for the factfinder to determine whether a particular collection of data was sufficiently aposematic to place an investor on inquiry notice."); *Marks v. CDW Computer Centers, Inc.*, 122 F.3d 363, 368-69 (7th Cir. 1997) (trier of fact should typically determine when the statute of limitations should begin to run).

Although there may doubtless be cases where the facts are sufficiently clear for a Court to state with confidence what a reasonable investor knew or should have known, this case assuredly is not one of them. Indeed, Petitioners' brief nowhere identified what "facts" could and should have been discovered prior to November 6, 2001 that would have caused reasonable investors to conclude that they had been defrauded. In the absence of such a showing, there is no basis whatever for this Court to conclude that Merck, as a matter of law, has established its affirmative statute of limitations defense.

CONCLUSION

NASCAT submits that for the foregoing reasons, Merck's proposed interpretation of the statute of limitations should be rejected and the judgment of the Third Circuit affirmed. Any interpretation of the statute of limitations provision should take into account the importance of private securities litigation as a supplement to government enforcement as well as the massive corporate scandals that continue to infect this nation's capital markets.

Dated: October 26, 2009

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AMICUS CURIAE BRIEF

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MERCK & CO., INC., *et al.*,
Petitioners,

v.

RICHARD REYNOLDS, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE NATIONAL COORDINATING COMMITTEE FOR MULTIEMPLOYER PLANS AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICUS CURIAE*

The National Coordinating Committee for Multiemployer Plans ("NCCMP") is a nonprofit, tax-exempt organization that has participated for over thirty years in the development of the law applicable to employee benefit plans.[1] The NCCMP numbers hundreds of multiemployer plans and related organizations among its membership, and it represents their interests in Congress, in rulemaking and in judicial proceedings. The NCCMP has filed numerous *amicus* briefs in this Court advocating for the rights of its members and of the millions of participants and beneficiaries who depend on multiemployer plans for their basic needs.

Pursuant to the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §§ 1001-1169, the benefits provided to the participants and beneficiaries of multiemployer plans are financed through trusts. 29 U.S.C. § 1103(a). To ensure the soundness of plans and their continuing ability to fund benefits, it is commonplace—indeed a practical necessity—that plan assets be invested in securities regulated by the Securities and Exchange Commission. Pension funds affiliated with the NCCMP have billions of dollars invested in the market. The ability of plans to protect those investments from fraudulent practices is a matter of vital concern to the NCCMP.

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[1] Pursuant to Rule 37.6 of the Rules of this Court, the undersigned hereby state that no counsel for Petitioners or Respondents authored any part of this brief. Moreover, no person or entity other than the NCCMP made a monetary contribution to the preparation or submission of this brief. Letters from the parties consenting to the filing of all *amicus* briefs have been filed with the Clerk of the Court.

In accordance with Section 302(c)(5)(B) of the Labor Management Relations Act, 29 U.S.C. § 186(c)(5)(B), multiemployer plans are governed by boards of trustees composed of representatives half of whom are appointed by labor and half by management. Those trustees exercise fiduciary duties with respect to plan assets, and are expected to hold, invest and protect fund assets for the benefit of participants and beneficiaries. 29 U.S.C. §§ 1102(a)(2), 1104(a)(1). Multiemployer plan trustees are typically laypersons who make investment decisions with the advice and guidance of investment advisors; such trustees are held to a prudence standard in developing and monitoring a fund's investment program. 29 U.S.C. § 1104(a)(1)(B).

Prudent trustees take seriously their obligation to monitor the performance of fund investments, but they must be equally mindful of the need to keep administrative costs to a reasonable level. If questions do arise concerning possible securities fraud under Section 10(b) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. § 78j(b) and Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5, plan trustees may find themselves in the role of potential plaintiffs in private securities fraud litigation, and possibly of class representatives and/or lead plaintiffs under the provisions of the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4. Such actions are governed by the statute of limitations set forth in 28 U.S.C. § 1658(b), which requires that an action be brought within two years after discovery of the facts constituting the violation or five years after the violation, whichever is earlier.

When faced with a potential securities fraud violation, multiemployer plan trustees must consider the

facts at their disposal and determine whether it is a prudent investment of fund assets to explore the possibility of fraud and and/or to retain counsel to consider or pursue litigation. These are not decisions lightly made, in view of the administrative costs involved in these undertakings. However, in some circumstances it may become appropriate for plan trustees to commence litigation to remedy losses to fund assets occasioned by violations of the Act.

The positions asserted in this case by Petitioners and their *amici* would, if adopted by the Court, place multiemployer fund trustees in an untenable position when losses have been suffered as a result of well concealed securities fraud violations. The NCCMP, its member plans, and their trustees, participants and beneficiaries, have a strong interest in a rule of law which will allow trustees a reasonable opportunity to make inquiry once put on notice that the necessary elements of a cause of action may exist warranting legal action. Likewise, they have a strong interest in a rule of law which will not require trustees to choose between filing precipitous lawsuits and foregoing claims that may eventually prove to be meritorious.

Accordingly, the NCCMP urges the Court to affirm the result below and to adopt a limitations rule which will allow multiemployer plan trustees a full opportunity to flesh out and where appropriate litigate—with the necessary facts at hand—actions under Section 10(b) of the Act.

SUMMARY OF ARGUMENT

Private actions under Section 10(b) of the Act must be filed within two years after "the discovery of the facts constituting the violation." 28 U.S.C. § 1658(b). In federal statutes with similarly worded limitations periods, this Court has held that both actual and constructive discovery can trigger the running of the statute. *E.g., Kirby v. Lake Shore & Mich. S. R.R.*, 120 U.S. 130, 134-36 (1887). Acting on the assumption that the Court would similarly construe Section 10(b) of the Act, the courts of appeals have developed analytic frameworks for determining when a plaintiff is held to have been on constructive notice of the facts constituting the violation.

It is the NCCMP's position that, at a minimum, a multiemployer plan board of trustees cannot be held to be on constructive notice of a Section 10(b) violation until at least two events have occurred. First, they have received information so suggestive of possible wrongdoing, and covering each element of the Section 10(b) claim—including *scienter*—that they would reasonably have made inquiry to determine whether the fund had a legal claim. Second, the trustees have discovered, or in the exercise of reasonable diligence would have discovered, facts that—if pled in a securities fraud complaint that complies with the pleading requirements of the PSLRA—would be sufficient to survive a motion to dismiss. Until trustees are in, or reasonably could have been in, a position to file such a complaint, the two year limitations period should not commence to run, irrespective of whether they actually undertook

their own investigation upon learning of storm warnings suggestive of fraud.[2]

As discussed below, any more restrictive reading of the limitations period for securities fraud claims would seriously handicap trustees in their ability to make prudent decisions regarding the expenditure of fund assets and the preservation of meritorious claims.

ARGUMENT

I. IN CASES OF "CONSTRUCTIVE" DISCOVERY OF THE FACTS CONSTITUTING A SECTION 10(B) VIOLATION, THE LIMITATIONS PERIOD SHOULD NOT COMMENCE TO RUN UNTIL, AT A MINIMUM, A) PLAN TRUSTEES HAVE INFORMATION, INCLUDING INFORMATION PERTAINING TO *SCIENTER*, THAT IS SO SUGGESTIVE OF POSSIBLE WRONG-DOING THAT THEY WOULD REASONABLY HAVE UNDERTAKEN FURTHER INQUIRY TO DETERMINE WHETHER THE FUND HAD A LEGAL CLAIM, AND B) THE TRUSTEES HAVE DISCOVERED, OR

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[2] Although the question is not presented in this case, *see* Brief for Respondents at 22 note 6, the NCCMP strongly disagrees with the position of Merck that potential trustee plaintiffs can be deemed "on notice for purposes of Section 1658(b)" prior to learning that the fund has suffered a loss cognizable under Section 10(b). *See* Brief for Petitioners at 29. Merck's suggestion seemingly would mean that a fund's limitations period could expire prior to the trustees learning of any loss in the value of fund assets. It is the loss, however, that will necessarily inform plan fiduciaries of the possibility of a violation and prompt further inquiry. The Court should reject any approach which would require trustees to expend trust assets in exploring and/or filing premature lawsuits absent any evidence of the necessary "loss" element of the Section 10(b) cause of action.

IN THE EXERCISE OF REASONABLE DILIGENCE WOULD HAVE DISCOVERED, FACTS THAT IF PLED IN A SECURITIES FRAUD COMPLAINT WOULD BE SUFFICIENT TO WITHSTAND A MOTION TO DISMISS.

A. Requiring fund trustees to preserve potential causes of action for securities fraud by forcing them to investigate such claims even when they have no information suggesting *scienter* would unduly deplete the resources of pension and welfare plans and/or disable them from vindicating losses caused by wrongdoing.

Multiemployer fund trustees, generally laypersons working in other, full-time jobs, have a myriad of responsibilities as the named fiduciaries of the plans they serve. They must deal not only with investment decisions and benefit claims, but actuarial determinations, plan design and amendments, benefit enhancements and reductions, compliance with statutory and regulatory schemes such as ERISA and the Internal Revenue Code, and numerous other aspects of plan administration. While trustees typically hire investment managers, actuaries, third party administrators, attorneys and other service providers to assist them in carrying out their fiduciary functions, they remain under an obligation to exercise prudence in the selection and monitoring of such professionals. Ultimately, the trustees must be mindful of their obligation to expend fund assets for the exclusive purpose of providing benefits to participants and beneficiaries and defraying "reasonable" expenses of plan administration. 29 U.S.C. § 1104(a)(1)(A).

When should such fund trustees, who are juggling an array of responsibilities in addition to monitoring the performance of the various investments in the fund's portfolio, be reasonably deemed to be on "inquiry notice" of a Section 10(b) claim? Clearly, the mere loss in value of a security standing alone cannot be deemed to put trustees on notice of the possibility of securities fraud. The elements of a viable Section 10(b) claim include (1) a material omission or misrepresentation, or the use of a manipulative or deceptive device or contrivance, (2) *scienter*, (3) a connection with the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation (a causal connection between the misrepresentation or deceptive device and the loss). *See Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005).

The element of *scienter*, at issue in this case, requires proof of "a mental state embracing intent to deceive, manipulate or defraud." *See Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 n.12 (1976). Under section 21D(b)(2) of the PSLRA, a private plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" when pleading a securities fraud violation. 15 U.S.C. §78u-4(b)(2). If plan trustees are deemed to be on inquiry notice of possible fraudulent conduct at points in time when they have no information suggestive of *scienter* then they seemingly must expend fund assets on fishing expeditions which may reap little or no benefit for plan participants. This would create a tension between the trustees' ability to husband plan assets and their vigilance to preserve potential claims for losses due to securities fraud.

In several respects at least, multiemployer plans are the classic type of institutional investor whose participation in securities fraud actions Congress has sought to encourage. In seeking to eliminate abusive practices in securities litigation, Congress enacted detailed "lead plaintiff procedures" in the PSLRA requiring the appointment in a private securities class action of a "lead plaintiff" who is "the member . . . of the purported plaintiff class that the court determines to be most capable of adequately representing the interests of class members." 15 U.S.C § 78u-4(a)(3)(B)(i). The major purpose behind this provision was to encourage institutional investors, such as the plans affiliated with the NCCMP, to assume leadership roles in securities class actions. *See* H.R. Conf. Rep. No. 104-369, 104th Cong., 1st Sess. at 34, *reprinted in* 1995 U.S.C.C.A.N. 733 (1995) (noting that the PSLRA was enacted to increase the likelihood that institutional investors and other class members with large amounts at stake would serve as lead plaintiffs and explaining that "increasing the role of institutional investors in class actions will ultimately benefit shareholders and assist courts by improving the quality of representation in securities class actions.")

Requiring trustees, as a condition of becoming eventual plaintiffs, to make questionable expenditures of fund assets in the investigation of claims as to which no information suggesting *scienter* is known will clearly deter this particular group of institutional investors from serving as lead plaintiffs, contrary to Congressional intent in the PSLRA. Moreover, such a reading of the limitations period would be at odds with Congress's express desire in the Multiemployer Pension Plan Amendments Act of 1980 ("MPPAA"), Pub. L. 96-364, 94 Stat. 1208, 1209-

10 (1980), to enhance the financial soundness of multiemployer pension plans and to foster their maintenance and growth. *See* MPPAA § 3, 29 U.S.C. § 1001a; H.R. Rep. No. 96-869, 96th Cong., 2d Sess., pt. 1, *reprinted in* 1980 U.S.C.C.A.N. 2918 (1980) (Report of the House of Representatives Committee on Education and Labor on H.R. 3904). These plans should not have to choose between spending fund assets on potentially fruitless investigations, on the one hand, and preserving the right to recover economic losses caused by successfully concealed fraudulent activity on the other.

Accordingly, it is the position of the NCCMP that information suggestive of *scienter* is a necessary component of inquiry notice.

B. The two year limitations period should not begin to run until, at a minimum, following inquiry notice, fund trustees have discovered, or through the exercise of reasonable diligence would have discovered, facts that if pled in a securities fraud complaint would be sufficient to withstand a motion to dismiss.

The determination of when the two year limitations period commences to run must necessarily take into consideration the special and stringent pleading requirements of the PSLRA. The Act requires a plaintiff to specify each statement alleged to have been misleading, as well as the reasons why the statement is misleading, and—if an allegation regarding the statement or omission is made on information and belief—to state with particularity all facts on which that belief is formed. 15 U.S.C. § 78u-4(b)(1)(B). Further, "with respect to each act or

omission alleged to violate this chapter," a plaintiff must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2).

In *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007), the Court noted that the PSLRA's "strong inference" standard "'unequivocally raise[d] the bar for pleading scienter . . . .'" 551 U.S. at 321, *quoting Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 437 F.3d 588, 601 (7th Cir. 2006). Under *Tellabs*, in determining whether a plaintiff has met the heightened pleading requirements pertaining to *scienter*, a reviewing court must engage in "a comparative evaluation" which considers not only the inferences urged by the plaintiff, but also any "competing inferences rationally drawn from the facts alleged." 551 U.S. at 314. To survive a motion to dismiss, the allegations of the complaint must be such that "a reasonable person would deem the inference of scienter cogent and at least as compelling" as any "plausible nonculpable explanations for the defendant's conduct . . . ." Id. at 324.

An investor who has merely been put on "inquiry notice" that a potential defendant may have acted with *scienter* in making misrepresentations forming the basis of a securities fraud claim thus still faces a significant hurdle in unearthing and pleading sufficient facts to survive a motion to dismiss. As is demonstrated in the case at bar, it can take years before facts sufficiently probative of a company's intent to deceive see the light of day. Congress did not intend in the PSLRA to stop meritorious suits from going forward; it simply enhanced the pleading standards by requiring a plaintiff to muster facts

raising a "cogent and compelling" inference of *scienter* before commencing litigation. *Id.*

Until such facts have been mustered, or reasonably could have been mustered, the two year limitations period cannot logically begin to run. The contrary rule urged by Petitioners and their *amici*—as even they concede—could operate to force plaintiffs to file suit before they are in possession of the minimum necessary facts to avoid dismissal. *E.g.*, Brief for the Petitioners at 31 (acknowledging that, under Petitioners' analysis, a plaintiff may be unable to file a complaint sufficient to withstand a motion to dismiss until after the statute of limitations has expired.) This would almost certainly mean forfeiture of claims, an absurd and unnecessary result. An interpretation allowing plan trustees, at a minimum, two years from discovery of the facts comprising the violation, *i.e.*, facts sufficient to defeat a motion to dismiss, is both sensible and faithful to the express language of 28 U.S.C. § 1658(b).

Private enforcement of federal antifraud securities laws is an important supplement to the regulatory efforts of the Department of Justice and the Securities and Exchange Commission. *See Dura Pharmaceuticals Inc. v. Broudo*, 544 U.S. 336, 345 (2005); *J.I. Case Co. v. Borak*, 377 U.S. 426, 432 (1964). Indeed, private securities litigation is "'an indispensable tool with which defrauded investors can recover their losses'—a matter crucial to the integrity of domestic capital markets." *See Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 321 n.4 (2007), *quoting Merrill Lynch Pierce Fenner & Smith v. Dabit*, 547 U.S. 71, 81 (2006). Thus there is a significant public interest in allowing institutional investors, such as those affiliated with the NCCMP, a reasonable oppor-

tunity to develop and pursue meritorious actions under Section 10(b).

As discussed above, the special fiduciary responsibilities of multiemployer plan trustees to protect and preserve trust assets, and their occasional need to pursue claims for misconduct that have resulted in losses to the trust, likewise militate for an interpretation of the statute of limitations that allows them a fair opportunity to address possible securities fraud claims. Prudent fund management would be seriously undermined by a rule that required trustees to choose between expensive and potentially fruitless rushes to the courthouse and possible permanent loss of as yet inchoate claims. These trusts, it should be emphasized, are the source of pension, medical and other benefits for millions of Americans. A diminishment in the value of trust assets can affect participants and beneficiaries in their daily lives.

These considerations clearly favor allowing trustees a reasonable opportunity to discover facts sufficient to survive a motion to dismiss before the two year period begins to run. They also disfavor the suggestion of some of Petitioners' *amici* that an investor who—upon inquiry notice—does not promptly commence an independent investigation is time-barred at the moment inquiry notice was received. *See, e.g.*, Brief for the Chamber of Commerce of the United States of America Supporting Petitioners at 25-26; Brief of the Securities Industry and Financial Markets Association as *Amicus Curiae* in Support of Petitioners at 8; Brief of DRI—The Voice of the Defense Bar as *Amicus Curiae* in Support of Petitioners at 2. Such a rule would impose new, cumbersome and unwarranted pleadings requirements on plaintiffs. *See, e.g.*, Brief of the Securities

Industry and Financial Markets Association as *Amicus Curiae* in Support of Petitioners at 8 (plaintiff would have to plead what investigatory steps it took, what it discovered and when, and what specific newly discovered facts now enable it to plead *scienter*.) Such a rule would also force multiemployer plan trustees, large or small, to expend fund assets on potentially fruitless investigations every time a "storm warning" appeared, or risk forfeiting meritorious securities fraud actions.

Petitioners' *amici* suggest that the equities disfavor a so-called "dilatory" plaintiff who does not immediately mount his own investigation of any conceivable fraud claim. *See, e.g.*, Brief for the Chamber of Commerce of the United States of America Supporting Petitioners at 25-26; Brief of DRI—The Voice of the Defense Bar as *Amicus Curiae* in Support of Petitioners at 2. Such a sweeping generalization fails to account for the fact that it may not be prudent for trustees to chase down every conceivable wrongdoing that may have diminished the value of a security. In any event, the balance of the equities surely favors a multiemployer fund that did not mount a hunting expedition upon the first sighting of a stormcloud, as opposed to a corporation the full scope of whose deceitful conduct has been shrouded in secrecy to the detriment of its investors.

CONCLUSION

For the reasons stated above, the result below should be affirmed.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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In the Supreme Court of the United States

MERCK & CO., INC., et al.,
Petitioners,

v.

RICHARD REYNOLDS, et al.,
Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF OHIO AND 25 OTHER STATES AND COMMONWEALTHS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Under 28 U.S.C. § 1658(b)(1), a limitations period of two years for a private securities-fraud action commences with "the discovery of the facts constituting the violation." The questions presented are:

1. Whether a reasonable Merck investor should have discovered petitioners' statements were material misrepresentations of belief and opinion as charged in respondents' complaint earlier than November 6, 2001?

2. Whether scienter is among the "facts constituting [a] violation" within the meaning of § 1658(B)(1); and, if so, whether a reasonable Merck investor should have discovered petitioners' fraudulent intent earlier than November 6, 2001?

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STATEMENT OF AMICI INTEREST

The amici States have a direct interest in the outcome of this appeal. To begin with, the amici States themselves are investors, representing some of the largest institutional investors in the world. As such, the States have a strong interest in protecting their citizens from securities fraud.

To that end, Congress has unmistakably favored large institutional investors like the States in securities-fraud litigation. When it was enacted in 1995, the Private Securities Litigation Reform Act ("PSLRA"), Pub. L. No. 104-67, 109 Stat.737, 15 U.S.C. § 78u-4(a)(3), et seq., shifted the focus and responsibility for private securities class actions to large institutional investors such as state pension funds. The statute's lead-plaintiff provision, 15 U.S.C. § 78u-4(a)(3)(B), directs courts to prefer "the most sophisticated investor available and willing to so serve in a putative securities class action." *Berger v. Compaq Computer Corp.*, 279 F.3d 313 (5th Cir. 2002) (per curiam); see also H.R. Rep. No. 104-369, at 34 (1995), reprinted in 1995 U.S.C.C.A.N. 733. Congress sensibly believed that, because these investors were among America's largest shareholders and stood to benefit the most from reforms that encouraged meritorious securities-fraud litigation, S. Rep. No. 104-98, at 36 (1995), reprinted in 1995 U.S.C.C.A.N. 714; H.R. Rep. No. 104-369, at 34 (1995), reprinted in 1995 U.S.C.C.A.N. 712-13, giving them lead-plaintiff status would balance the interests of the class with the long-term interests of the company and its public investors. S. Rep. No. 104-98, at 34 (1995), reprinted in 1995 U.S.C.C.A.N 713. This preference also allows larger investors

with greater resources to look out for the interests of smaller, individual investors.

As a result, courts often appoint public pension funds to a lead-plaintiff position because the entities are stable, have the largest losses associated with the alleged fraud, and are financially able to commit substantial resources to litigation. For instance, a district court recently designated state pension funds, including Ohio's, among three lead plaintiffs in a suit concerning Bank of America's merger with Merrill Lynch, explaining that the funds "have the greatest financial interest in the outcome of the case, their interests appear to be otherwise aligned with those of the putative class, and they have retained competent and experienced counsel." *In re Bank of Am. Corp. Sec., Deriv. & ERISA Litig.*, No. 09-MDL-2058, 2009 U.S. Dist. Lexis 56009, at *24 (S.D.N.Y. June 30, 2009); see also *In re Cardinal Health, Inc. Sec. Litig.*, 226 F.R.D. 298, 311 (S.D. Ohio 2005); *In re Vicuron Pharms., Inc. Sec. Litig.*, 225 F.R.D. 508, 512 (E.D. Pa. 2004).

The amici States also have a stake in the integrity and competitiveness of the securities markets from the vantage point of public protection. For the markets to function properly, fraudulent actors of all types must be deterred. The States accordingly are keenly interested in ensuring that the securities laws continue to guard against fraudulent activity.

SUMMARY OF ARGUMENT

For all of Petitioner Merck & Co.'s discussion of scienter, this case easily can and should be resolved on a different theory. Merck acknowledges that equitable principles apply here, but what Merck does not say is that this case fits neatly within the well-settled "words of comfort" doctrine. Widely recognized by federal and state courts both within and outside of the securities-fraud context, this equitable doctrine holds that a company's reassuring statements—its words of comfort—can offset any negative events or information (commonly called "storm warnings") that would trigger the accrual of a securities-fraud claim.

The Third Circuit's analysis below is fully consistent with the words-of-comfort doctrine. The court correctly found that sufficient factual questions exist to deny Merck's motion to dismiss on limitations-period grounds. Namely, Merck's repeated and detailed public assertions about the naproxen hypothesis may have allayed any concerns that a reasonable investor would have had about the higher incidence of cardiovascular events related to its drug Vioxx.

Even if Merck's words of comfort did not mitigate the storm warnings (assuming any existed) about the naproxen hypothesis, however, there is another reason to affirm the Third Circuit's opinion. The statute of limitations does not begin to run on a securities-fraud claim until the point at which a reasonable investor conducting a reasonably diligent inquiry would have uncovered the fraud. See, e.g., *Wyser-Pratte Mgmt. Co., Inc. v. Telxon Corp.*, 413 F.3d 553, 562-63 (6th Cir. 2005). That objective

standard advances Congress's intent to reduce strike suits by favoring large institutional investors, such as public pension funds, that cannot, and should not, be expected constantly to undertake actual investigations of storm warnings. And when the objective test is applied to this case, at the very least, a factual question exists on the question of when Respondents' claim accrued.

ARGUMENT

A. Words of comfort allayed any potential storm warnings regarding the safety of Vioxx.

All parties and the Third Circuit appear to agree on the basic securities-fraud concepts at issue in this case—inquiry notice and storm warnings. As Merck puts it, "a plaintiff is on inquiry notice when he receives so-called 'storm warnings': *i.e.*, when there was sufficient information in the plaintiff's possession, or in the public domain, to cause a reasonable investor to suspect the possibility that the defendant had engaged in securities fraud." Pet. Br. at 21; accord Pet. App. 23a-24a; Opp. to Cert. at 15. The circuit courts widely agree on this analytical framework. See *Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 876 (9th Cir. 2008); *Staehr v. Hartford Fin. Servs. Group, Inc.*, 547 F.3d 406, 411 (2d Cir. 2008); *Sudo Props., Inc. v. Terrebone Parish Consol. Gov't*, 503 F.3d 371, 376 (5th Cir. 2007); *Tello v. Dean Witter Reynolds, Inc.*, 410 F.3d 1275, 1283 (11th Cir. 2005) ("*Tello I*"); *New England Health Care Employees Pension Fund v. Ernst & Young, LLP*, 336 F.3d 495, 501 (6th Cir. 2003); *Young v. Lepone*, 305 F.3d 1, 8 (1st Cir. 2002); *Ritchey v. Horner*, 244 F.3d 635, 638-39 (8th Cir. 2001); *Kauther SDN BHD v.*

Sternberg, 149 F.3d 659, 670 (7th Cir. 1998); *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1198 (10th Cir. 1998); *Brumbaugh v. Princeton Partners*, 985 F.2d 157, 162 (4th Cir. 1993).

Despite this agreement, Merck maintains that the Third Circuit's approach "would essentially render the principle of inquiry notice a dead letter." Pet. Br. at 14. Yet it is reversal, not affirmance, that would change the landscape of federal securities litigation. The Third Circuit simply applied longstanding equitable principles to find that Merck's public and repeated assurances regarding the safety of Vioxx raised questions about the degree to which reasonable investors should have been on inquiry notice. That analysis fits easily within the widely recognized words-of-comfort doctrine.

1. Federal courts widely recognize that words of comfort may allay storm warnings of fraud.

The words-of-comfort doctrine is a well-settled exception to the inquiry-notice rule. Simply put, the doctrine holds that a defendant's reassuring statements or persistent denials may mitigate negative events or disclosures to such a degree that a plaintiff is not on sufficient notice to investigate the possibility of fraud.

The inquiry-notice rule is founded on the proposition that an investor has a duty of inquiry "when the circumstances would suggest to an investor of ordinary intelligence that she has been defrauded." *Dodds v. Cigna Sec., Inc.*, 12 F.3d 346, 350 (2d Cir. 1993). But a defendant's actions can mitigate that duty. Specifically, "[t]here are

occasions when, despite the presence of some ominous indicators, investors may not be considered to have been placed on inquiry notice because the warnings signs are accompanied by reliable *words of comfort* from management." *LC Capital Partners, L.P. v. Frontier Ins. Group, Inc.*, 318 F.3d 148, 155 (2d Cir. 2003) (emphasis added). "Such statements are among the factors that must be considered when evaluating whether" a reasonable investor would have been on inquiry notice. *Id.*

The Second Circuit has described the type of statements that qualify as words of comfort, explaining that "reassuring statements will prevent the emergence of a duty to inquire or dissipate such a duty only if an investor of ordinary intelligence would reasonably rely on the statements to allay the investor's concern." *Id.* Whether statements rise to this level "will depend in large part on how significant the company's disclosed problems are, how likely they are of a recurring nature, and how substantial are the 'reassuring' steps announced to avoid their recurrence." *Id.* For instance, "'[s]tatements of cautious optimism, reiterations of the goal of providing income to investors, and explanations for past poor performance'" are not enough. *Id.* (citing *Farr v. Shearson Lehman Hutton, Inc.*, 755 F. Supp. 1219, 1228 (S.D.N.Y. 1991)).

The lower courts widely agree on the words-of-comfort doctrine in the securities-fraud context. The Fifth Circuit, for instance, has held that a jury question existed regarding inquiry notice where the defendant's representations counteracted negative information available to investors. See *Sudo Props.*, 503 F.3d at 376-77. The Ninth Circuit has taken the

same approach. *Gray v. First Winthrop Corp.*, 82 F.3d 877, 882-83 (9th Cir. 1996) (holding that a jury should determine if the statute of limitations had run where all negative financial information was coupled with defendant's reassurances of the health of the investment). Other courts are similarly "reluctant to find that the plaintiffs were on inquiry notice of their claims" where "there is a mix of information available to the plaintiffs such that any negative statements are tempered by positive statements from a company's management and others." *In re DaimlerChrysler AG Sec. Litig.*, 269 F. Supp. 2d 508, 514 (D. Del. 2003); see, e.g., *In re Moody's Corp. Sec. Litig.*, 599 F. Supp. 2d 493, 506 (S.D.N.Y. 2009); *Cohen v. N.W. Growth Corp.*, 385 F. Supp. 2d 935, 946 (D.S.D. 2005); *In re Dynegy, Inc. Sec. Litig.*, 339 F. Supp. 2d 804, 850 (S.D. Tex. 2004); *Bovee v. Coopers & Lybrand*, 320 F. Supp. 2d 646, 655-56 (S.D. Ohio 2004); *Fugman v. Apogenex, Inc.* 961 F. Supp. 1190, 1196-98 (N.D. Ill. 1997).

Courts also recognize the principle that words of comfort dissipate storm warnings outside of the securities-fraud context. Petitioners acknowledge that, at common law, statute of limitations for fraud claims are subject to equitable principles such as the discovery rule. Pet. Br. at 16. The words-of-comfort doctrine is simply an extension of equitable principles recognizing that a defendant should not benefit from a limitations bar by falsely reassuring a plaintiff that no fraud occurred. See *Dodds*, 12 F.3d at 350 (explaining that equitable tolling will stay the running of the statute of limitations only so long as the plaintiff has "exercised reasonable care and diligence in seeking to learn the facts which would disclose fraud") (citing *Arneil v. Ramsey*, 550 F.2d

774, 781 (2d Cir. 1977) (quoting *Morgan v. Koch*, 419 F.2d 933, 997 (7th Cir. 1969))); see also *Vucinich v. Paine, Webber, Jackson & Curtis, Inc.*, 739 F.2d 1434, 1436-37 (9th Cir. 1984). The doctrine is therefore applied in a wide range of federal and state cases.

Words of comfort frequently toll the limitations period in the malpractice context. In medical malpractice actions brought under the Federal Tort Claims Act, for instance, federal courts consistently toll the statute of limitations for plaintiffs who reasonably relied on the assurances of physicians alleged to have committed malpractice. See, e.g., *McDonald v. United States*, 843 F.2d 247, 248-49 (6th Cir. 1988); *Colleen v. United States*, 843 F.2d 329 (9th Cir. 1987); *Raddatz v. United States*, 750 F.2d 791, 796 (9th Cir. 1984). State courts likewise hold in medical malpractice cases that reasonable assurances by the alleged wrongdoer may toll the statute of limitations. See, e.g., *Gaston v. Parsons*, 864 P.2d 1319, 1324 (Or. 1994); *Herr v. Robinson Mem'l Hosp.*, 550 N.E.2d 159, 161-62 (Ohio 1990). Similarly, in legal malpractice actions, a lawyer's false assurances can delay the point at which a client can reasonably discover the lawyer's malpractice, thereby tolling the statute of limitations. See, e.g., *Frederick Rd. Ltd. P'ship v. Brown & Sturm*, 756 A.2d 963, 976 (Md. Ct. App. 2000); *Hoeck v. Schwabe, Williamson & Wyatt*, 945 P.2d 534, 538 (Or. Ct. App. 1997); *Koch v. Gross*, 582 N.E.2d 51, 54 (Ohio Ct. App. 1990).

The rule holds true for other tort claims as well. For example, reliance on the defendant's assurances can toll the statute of limitations in products-liability

actions. See, e.g., *Reed v. Gen. Motors Corp.*, 400 So.2d 919, 920-21 (La. Ct. App. 1981) (holding that the limitations period for a car owner did not accrue at the time of an accident because after repairing the car, the seller assured the owner that no problem existed and that there would be no future problems). State courts apply a similar analysis to breach-of-warranty claims. See, e.g., *Forest Grove Brick Works, Inc. v. Strickland*, 559 P.2d 502, 506 (Or. 1977) (reversing grant of summary judgment for seller of defective industrial vacuum pump where seller's continued false assurances to buyer that the pump would meet his needs created a question as to whether the statute of limitations on buyer's claim had run).

In the same vein, both federal and state Racketeer Influenced and Corrupt Organizations ("RICO") laws consider the effect of a defendant's reassurances to determine when a claim accrues. Federal courts addressing RICO claims suggest that assurances made by an investment's promoter or manager may toll the limitations period depending on the surrounding storm warnings. See, e.g., *Cetel v. Kirwan Fin. Group, Inc.*, 460 F.3d 494, 508-09 (3d Cir. 2006). In a state RICO action, assurances by a broker created an issue of fact as to whether the broker lulled investors into a false sense of security, precluding the investors from discovering that they may have a cause of action against the broker. *Penuel v. Titan/Value Equities Group*, 872 P.2d 28, 31-32 (Or. Ct. App. 1994).

The words-of-comfort doctrine is therefore in step with broader equitable principles that have long governed the limitations-period analysis for

securities-fraud claims. Courts routinely determine that the statute of limitations on a plaintiff's securities-fraud claim has not begun to run because a company's reassuring statements gave investors a reason not to investigate further.

2. The existence of inquiry notice is a highly fact-bound inquiry that is inappropriate for determination on a motion to dismiss.

Whether storm warnings sufficed to trigger the limitations period—or whether, on the other hand, words of comfort prevented a claim from accruing—is a highly factual determination. As such, the determination is rarely appropriate for resolution on a Rule 12(b)(6) motion to dismiss.

The federal courts of appeals have recognized "the fact-specific nature of the limitations defense, particularly where the claim is foreclosed by inquiry notice." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 169 (2d Cir. 2005). As Judge Posner has explained, "the facts constituting [inquiry] notice must be sufficiently probative of fraud—sufficiently advanced beyond the stage of a mere suspicion, sufficiently confirmed or substantiated—not only to incite the victim to investigate but also to enable him to tie up any loose ends and complete the investigation in time to file a timely suit." *Fujisawa Pharm. Co. v. Kapoor*, 115 F.3d 1332, 1335 (7th Cir. 1997).

Given the fact-intensive nature of this inquiry, many appeals courts have held that resolution of inquiry notice at the pleading stage, and prior to substantial discovery, is often inappropriate. See *Sudo Props.*, 503 F.3d at 376 ("The 'fact-intensive'

inquiry of what constitutes inquiry notice 'is typically appropriate for consideration by a jury.'") (citation omitted); *La Grasta v. First Union Sec. Inc.*, 358 F.3d 840, 848 (11th Cir. 2004) ("Whether a plaintiff had sufficient facts to place him on inquiry notice of a claim for securities fraud . . . is a question of fact, and as such is often inappropriate for resolution on a motion to dismiss under Rule 12(b)(6)." (quoting *Marks v. CDW Computer Ctrs., Inc.*, 122 F.3d 363, 367 (7th Cir. 1997)); *LC Capital Partners, L.P.*, 318 F.3d at 156 ("We recognize whether a plaintiff had sufficient facts to place it on inquiry notice is often inappropriate for resolution on a motion to dismiss.") (internal quotes and citations omitted); *Kauther SDN BHD*, 149 F.3d at 669 (noting that "because the question of whether a plaintiff had sufficient facts to place it on inquiry notice of a claim for securities fraud is one of fact, it may be inappropriate for resolution on a motion to dismiss under Rule 12(b)(6)") (internal quotations omitted). Other decisions are in accord. See *Bovee*, 216 F.R.D. at 611; *Nappier v. PricewaterhouseCoopers LLP*, 227 F. Supp. 2d 263, 274-75 (D.N.J. 2002); *Wenneman v. Brown*, 49 F. Supp. 2d 1283, 1292 (D. Utah 1999).

To determine whether a plaintiff investor was on inquiry notice, then, a court must undertake a highly fact-bound analysis and ordinarily should allow further factual development beyond a motion to dismiss. The Third Circuit did precisely that in this case.

3. This case fits neatly within the words-of-comfort doctrine and withstands a motion to dismiss.

The Third Circuit's analysis is fully consistent with equitable tolling principles generally and the words-of-comfort doctrine specifically.

The Third Circuit carefully documented the ways Merck misled investors. The court noted that, as early as 1999, Merck began the Vioxx Gastrointestinal Outcomes Research ("VIGOR") study, which compared Vioxx to a comparator drug, naproxen. The VIGOR study indicated that "Vioxx users had a higher incidence of [cardiovascular] events than naproxen users." Pet. App. 6a. In response to the VIGOR study, Merck touted the "naproxen hypothesis" in a press release, asserting that Vioxx would be expected to have significantly favorable effects. Pet. App. 7a.

The Third Circuit also observed the host of ways in which Merck, between January 1999 and April 2002, countered a number of public disclosures regarding the higher incidence of heart attacks occurring in Vioxx users with public assertions that Vioxx was safe, and that the protective effects of naproxen explained the increased rate of cardiovascular events. See Pet. App. 36a-39a, 44a-46a. It was not until one year later, on November 1, 2004, that Merck's repeated confidence in the naproxen hypothesis was questioned by a *Wall Street Journal* article publishing e-mail excerpts from Merck scientists and executives discussing the adverse cardiovascular side effects of Vioxx. Pet. App. 18a-19a. See also Joint Appendix ("J.A.") at 191-97 (discussing contents of Merck's internal

e-mails. The Third Circuit noted in particular that Petitioner Scolnik, Merck's then-top scientist, asserted in a March 2000 e-mail (written shortly after the VIGOR study) that Vioxx's higher incidence of cardiovascular events "is a shame but it is a low incidence and it is mechanism based as we worried it was." Pet. App. 6a; J.A. at 192.

After reciting these reassurances and others, the Third Circuit noted the settled legal principles explained above—"that reassurances can dissipate apparent storm warnings if an investor of ordinary intelligence would reasonably rely on them to allay investor's concerns." Pet. App. 36a n.14 (citing *Benak v. Alliance Capital Mgmt., L.P.*, 435 F.3d 396, 402 n.16 (3d Cir. 2006)). The court concluded that "the District Court acted prematurely in finding as a matter of law that Appellants were on inquiry notice of the alleged fraud before October 9, 2001. As of that date, market analysts, scientists, the press, and even the FDA agreed that the naproxen hypothesis was "plausible, at the very least." Pet. App. 46a. "On the record before" it, the court found that investors had "no reason to suspect that Merck did not believe the naproxen hypothesis until the Harvard study in 2003 revealed an increased risk of heart attacks in patients taking Vioxx." Pet. App. 47a. Dismissal under Rule 12(b)(6), the court held, was therefore inappropriate. Pet App. at 48a.

The Third Circuit's analysis comports with other federal court decisions denying similar dismissal motions. See, e.g., *Sudo Props.*, 503 F.3d at 377-78; *In re Tyco Int'l, Ltd. MDL*, MDL No. 02-1335-B, 2004 U.S. Dist. Lexis 20733, at *57 (D.N.H. Oct. 14, 2004) (explaining that "a dispute about

whether sufficient storm warnings were present to deny the plaintiff the benefit of the discovery rule generally will not be resolvable on a motion to dismiss, unless it is plain from the complaint itself that the plaintiffs' claims are time-barred"); *In re Global Crossing, Ltd. Sec. Litig.*, 313 F. Supp. 2d 189, 204 (S.D.N.Y. 2003) (denying defendants' motion to dismiss and noting that whether a plaintiff is on inquiry notice is a "question of fact for ultimate resolution at trial (or on summary judgment if the factual record permits only one conclusion)"). The Complaint alleges that the naproxen hypothesis, aggressively touted by Merck, was the primary reason the investment community continued to believe the drug did not cause the cardiovascular events associated with it. Under the words-of-comfort doctrine, those allegations suffice to survive a defendant's motion to dismiss.

B. A reasonable investor performing a reasonably diligent investigation would not have uncovered Merck's fraud.

Federal courts generally use a two-step analysis to determine whether the statute of limitations for securities-fraud claims has started to run. See Pet. Br. at 18-19; Resp't. Br. in Opp'n. to Cert. at 9. As explained above, the first step is the inquiry-notice analysis—a highly fact-bound, objective determination as to whether a reasonable investor would have a duty to inquire into possible securities fraud. Because the words-of-comfort doctrine does not change the applicable standards for the inquiry-notice prong of the analysis, the Court can affirm the Third Circuit on this first step and leave it at that.

If the Court chooses to reach it, however, there is a second step—the investigation prong. Under that prong, the circuit courts generally hold that the statute of limitations on a securities-fraud claim does not begin to run unless a reasonably diligent investigation could have uncovered the specifics of the alleged fraud. Merck argues that the rule should be purely subjective—that "the limitations period begins to run from the date of inquiry notice" unless the plaintiff *actually* conducted a "reasonably diligent investigation" that failed to uncover the fraud. Pet. Br. at 39. Because Merck's preferred approach is inconsistent with the policies underlying the securities laws, however, the Court instead should agree with the majority of circuits and hold that a securities-fraud claim does not accrue until a *reasonable investor* performing a *reasonably diligent investigation* would have discovered the specifics of the fraud.

1. The purpose and policies underlying the securities laws require that a claim not accrue until a reasonably diligent investigation would have exposed the fraud.

The policies underlying the federal securities laws require a careful balance between protecting companies from unsupported or frivolous securities laws claims on the one hand, and allowing investors to seek recovery for losses from fraud on the other. See *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). In that vein, this Court's recent decisions have attempted to balance the competing interests of the plaintiff-investors and defendant-companies. See, e.g., *id.* at 322

(describing the PSLRA as having "twin goals: to curb frivolous, lawyer-driven litigation, while preserving investor's ability to recover on meritorious claims"); *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71, 81 (2006); *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 345 (2005).

That balance is reflected in part in the statute of limitations. In the wake of the Enron scandal, Congress enacted Section 804 of the Public Company Accounting Reform and Investor Protection Act of 2002, better known as the Sarbanes-Oxley Act. Pub. L. No. 107-204, § 804, 116 Stat. 745, 801 (codified in part at 28 U.S.C. § 1658 (2002)). One of Congress's purposes in enacting that law was to give plaintiffs additional time, in light of the complexity of securities-fraud cases, to investigate their claims. See, e.g., S. Rep. No. 107-146, at 17 (2002) (noting that "the current short statute of limitations may insulate the worst offenders from accountability" and could be considered "an invitation to take sophisticated steps to conceal the deceit").

The core purpose of the securities laws—to protect investors—is vindicated by the statute-of-limitations rule that the circuit courts follow. Ten federal appeals courts agree that "the limitation period begins to run only when a reasonably diligent investigation should have discovered the fraud." *New England Health Care Employees Pension Fund*, 336 F.3d 495, 501 (6th Cir. 2003); accord *Betz*, 519 F.3d at 870-71; *Sudo Props.*, 503 F.3d at 376; *Benak*, 435 F.3d at 400; *Tello I*, 410 F.3d at 1285-88, vacated on other grounds, *Tello v. Dean Witter Reynolds, Inc.*, 494 F.3d 956, 968 (11th Cir. 2007) ("*Tello II*"); *LC Capital Partners, L.P.*, 318 F.3d at 154; *Young*, 305

F.3d at 10; *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1201 (10th Cir. 1998); *Marks*, 122 F.3d at 367-68; *Great Rivers Coop. of S.W. Iowa v. Farmland Indus.*, 120 F.3d 893, 896 (8th Cir. 1997). As the Ninth Circuit has explained, a contrary rule would encourage premature, baseless suits because it would "requir[e] plaintiffs to sue before they can discover the facts underlying their claims." *Betz*, 519 F.3d at 870; accord *Lentell*, 396 F.3d at 168. The reasonable-investigation rule, by contrast, "reflect[s] an 'appropriate balance' between competing interests," *Wyser-Pratte Mgmt.*, 413 F.3d at 563, and "treats both plaintiffs and defendants even-handedly." *Young*, 305 F.3d at 9.

The reasonable-investigation approach also comports with broader equitable principles outside the securities-fraud context. Under the "discovery rule" common in state law, a limitations period does not begin to run until the injured party should have become aware of his injury through the exercise of reasonable diligence. In Ohio, for instance, courts have applied the discovery rule to toll the statute of limitations for various causes of action—including wrongful adoption, negligent credentialing of a physician, exposure to toxic gas, sexual abuse of children, and wrongful death—without requiring an actual investigation by plaintiffs. See *Harris v. Liston*, 714 N.E.2d 377, 378, 380 (Ohio 1999). Federal courts agree that the discovery rule "postpones the beginning of the limitations period from the date a plaintiff was wronged until the date a plaintiff discovers that he or she was injured." *Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1386 (3d Cir. 1994); see, e.g., *Local 219 Plumbing & Pipefitting Indus. Pension Fund v. Buck*

Consultants, L.L.C., 311 F. App'x 827, 829 (6th Cir. 2009); *Walker v. Epps*, 550 F.3d 407, 414 (5th Cir. 2008); *Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 590 (3d Cir. 2005).

Merck has not cited a single circuit court decision departing from the reasonable-investigation rule. Even the Fourth Circuit's statute-of-limitations analysis, which applies once a plaintiff is on inquiry notice, acknowledges that the occurrence of a reasonably diligent investigation may be an important consideration in determining whether such notice is triggered. See *Brumbaugh*, 985 F.2d at 162 ("The objective standard of due diligence requires reasonable investigation of the possibility of misrepresentation once an individual has been placed on inquiry notice of wrongdoing."). Accordingly, given the agreement among the circuits and the strong policy considerations underlying such a rule, the Court should hold that the clock does not begin to tick on a securities-fraud claim until a reasonably diligent investigation would have uncovered the alleged fraud.

2. The reasonable-investigation rule should be applied objectively from the perspective of a reasonable investor.

There remains the question whether the reasonable-investigation rule should be objective or subjective in nature. Merck advocates a subjective test that asks whether the plaintiff herself *actually* undertook a reasonably diligent investigation. Pet. Br. at 43, 44 n.13. The weight of the case law and strong policy considerations, however, militate in favor of an objective test that asks whether a

reasonable investor would have performed a reasonable investigation.

Although some variations exist under the reasonable-investor approach, most circuit courts agree that the investigation prong does not require that the actual plaintiff perform a reasonably diligent investigation. Some circuits conduct a purely objective inquiry, considering whether the reasonable investor, performing a reasonably diligent investigation, should have discovered the fraud. E.g., *New England Health Care Employees Pension Fund*, 336 F.3d at 501. In other circuits, the analysis is both subjective and objective: whether a reasonable investor, standing in the shoes of the actual plaintiff, would have exposed the fraud upon a reasonably diligent investigation. Those courts assess "the plaintiff's particular circumstances" but do not require that the actual plaintiff perform an actual investigation. *Betz*, 519 F.3d at 871; see also *Tello I*, 410 F.3d at 1283-84; *Sterlin*, 154 F.3d at 1201-02; *Marks*, 122 F.3d at 368; *Great Rivers Coop.*, 120 F.3d at 897.

Even those circuits that look to what the plaintiff actually did still ask what a reasonable investor's reasonable investigation would have uncovered. The Second and Third Circuits have indicated that the investigation prong requires the actual investor to "make some inquiry"; then, upon such a showing, the limitations-period begins to run on the date a "reasonable investor in the exercise of reasonable diligence should have discovered the fraud." *LC Capital Partners, L.P.*, 318 F.3d at 154; accord *Benak*, 435 F.3d at 400-01.

The reasonable-investor analysis fits with the purpose and policies underlying the securities laws. One of Congress's chief goals in enacting the PSLRA was to favor just what the reasonable-investor standard focuses on—*reasonable investors*. Congress designed the PSLRA to curtail securities class actions brought by "professional plaintiffs," litigants who repeatedly asserted "frivolous" fraud claims against corporations in the hope of negotiating quick settlements. H.R. Rep. No. 104-369, at 32-33 (1995), reprinted in 1995 U.S.C.C.A.N. 730, 731-32; *Dabit*, 547 U.S. at 81 (noting that Congress intended the PSLRA to combat "perceived abuses of the class-action vehicle"). Rampant "strike" suits created a host of problems. For instance, because lead counsel "historically chos[e] the lead plaintiff," *In re Cendent Corp. Sec. Litig.*, 404 F.3d 173, 192 (3d Cir. 2005), speed in the selection process replaced diligence. Attorneys for handpicked clients would attempt to secure lead-counsel appointments by filing hastily drafted, cookie-cutter complaints before legitimate claimants could sue.

Congress sought to remedy this problem by giving preference to large institutional investors—particularly public pension funds—as lead plaintiffs in major securities litigation. The aim was to "ensure that parties with significant financial interests in the litigation would oversee securities actions and control the management of such suits." *In re Bank of Am.*, 2009 U.S. Dist. Lexis 56009, at *24 (citation omitted); see also H.R. Rep. No. 104-369, at 32 (1995), reprinted in 1995 U.S.C.C.A.N. 730, 731. The PSLRA accordingly increased the likelihood that institutional investors would serve as lead plaintiffs in securities class actions, decreasing

the number of these abusive suits. See *Tellabs*, 551 U.S. at 320-321; H.R. Rep. No. 104-369, at 34 (1995), reprinted in 1995 U.S.C.C.A.N. 733. In fact, public funds have been at the forefront of the largest investor recoveries ever awarded in securities-fraud litigation under the PSLRA. See, e.g., *In re Enron Corp. Sec. Litig.*, 206 F.R.D. 427, 458-59 (S.D. Tex. 2002); *Albert Fadem Trust v. Worldcom*, 2002 U.S. Dist. Lexis 15005, at *6 (S.D.N.Y. Aug. 15, 2002); see also Sec. Class Action Servs., RiskMetrics Group, *Top 100 Settlements Report* (2008), available at http://www.riskmetrics.com/knowledge/docs/SCAS100_2008 (last visited Oct. 15, 2009).

A limitations-period analysis that requires actual investigation is not consistent with this statutory preference for institutional investors. Fiduciary duties oblige the trustees of public funds to prudently invest fund assets, encouraging growth while minimizing risk. Although fraud monitoring is essential to fulfilling this responsibility, it cannot become trustees' tireless pursuit. Given the prohibitive costs of in-house fraud monitoring, public funds inherently depend upon third-party market professionals to analyze the value of fund investments. (Smaller individual investors, of course, lack the resources to rely on asset managers.)

Adopted in 2005, the statutory duties and internal policies and expenditures of the Ohio Public Employees' Retirement System ("OPERS") illustrate how such funds operate. Ohio law instructs the OPERS board of directors to invest its funds with "care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with these

matters would use in the conduct of an enterprise of a like character and with like aims." Ohio Rev. Code § 145.11(A) (2009). In keeping with these duties, the OPERS board of trustees is statutorily required to designate a chief investment officer to oversee the fund's investment officers, whose duties specifically include "the adoption, implementation, and enforcement of written policies and procedures reasonably designed to prevent persons employed by the public employees retirement system from misusing material, nonpublic information in violation of [federal and state] laws, rules, and regulations." *Id.* § 145.094(B). The chief investment officer must also monitor external transactions on behalf of the fund, *id.* § 145.094(C), and OPERS commits resources to monitoring the fund's external managers based upon the fund's overall performance.

Since 2007, OPERS's expenditures for legal and investigative actions have decreased significantly, but its net administrative expenses actually increased over the same time period. OPERS's allocation of resources demonstrates its belief that it best protects its fiduciaries' interests by investing greater amounts in consulting, investment, and financial services rather than in the investigation and litigation resources used during the recent period of market volatility. Institutional investors like OPERS find these administrative efforts to be more cost effective than constantly policing the market in an attempt to ferret out and prosecute fraud. The OPERS board manages roughly $60 billion in assets that are diversely invested in public and private equity, both domestic and foreign; hedge funds; real estate investment trusts; bonds; commercial paper; structured finance products; and

more. Monitoring the possibility of fraud by each company in which OPERS invests would be a monumental undertaking, to say the least.

Congress was well aware of this reality when it granted preference to institutional investors under the PSLRA. For Merck to suggest that such investors must undertake *actual* investigations of storm warnings is to ignore not only the manner in which such investors operate, but also the goals of the PSLRA. The Court should not craft a rule that undermines Congress's purposes by requiring pension funds to investigate every time negative information surfaces about one of the thousands of companies in which they are invested.

Nor is it feasible to require, as Merck suggests, that an actual investigation have been conducted, at the least, by plaintiff's *counsel* as a proxy. Pet. Br. at 45-46. Merck submits that such a requirement is reasonable given the "sophisticated plaintiffs' bar" that now exists in securities-fraud litigation. *Id.* But again Merck ignores the way large public pension funds approach such litigation. Large institutional investors like OPERS do not immediately retain counsel whenever suspicious signs of fraud arise. Rather, the initial investigation and drafting of the first complaints in a large securities class action occurs by plaintiff's counsel working with a smaller investor. Then, if such a claim has interest for a pension fund like OPERS, the PSLRA allows the fund to intervene by filing a motion for lead-plaintiff status based on the large losses suffered by the fund. See 15 U.S.C. § 78u-4(a)(3)(B)(iii)(I); see, e.g., *In re Bank of Am.*, 2009 U.S. Dist. Lexis 56009, at *20-21.

The decision process for intervening in such cases is a careful and deliberate one. A number of large public pension funds have established a competitive process to choose outside counsel to prepare the fund's lead-plaintiff motions and, if successful, represent the fund in litigation. In Ohio, for instance, the Ohio Attorney General, working with five large, separately managed public pension funds with over $120 billion in assets under management, has established a panel of prominent securities-litigation firms to submit proposals to represent one or more of the funds when the Attorney General and the funds decide that such litigation is appropriate. The process takes into account many factors, including, among others, the quality of the written proposal and the law firm's record of success. To satisfy Merck's actual-investigation rule, the pension funds would have to short-circuit that competitive process and retain counsel at the first inkling of fraud. Merck's approach would therefore undermine the very investors to whom Congress has shown favor.

Unlike the impracticable actual-investigation standard, experience shows that the reasonable-investor test is eminently workable. See, e.g., *Wyser-Pratte Mgmt.*, 413 F.3d at 564-65; *Fujisawa*, 115 F.3d at 1335-36. Merck suggests that "it would force courts to engage in entirely hypothetical inquiries about what a reasonably diligent investigation would have entailed and how long it would have taken for such an investigation to bear fruit." Pet. Br. at 50. But the "reasonable man" standard has deep roots in the common law. E.g., *Stoffel v. New York, N.H. & H.R. Co.*, 205 F.2d 411, 412 (2d Cir. 1953) (L. Hand, J.) (where a "reasonable man with due regard for his

own safety" would not have acted as plaintiff, plaintiff was guilty of contributory negligence as a matter of law). All evidence shows that courts are well equipped to apply such a standard.

3. The Third Circuit's opinion is consistent with the reasonable-investor/reasonable-investigation test.

Under the standard of a reasonable investor conducting a reasonable investigation, the Third Circuit reached the right outcome. Regardless of when inquiry notice was triggered, Merck's insistence on the naproxen hypothesis and its detailed and effective reassurances would have prevented a reasonable investor from uncovering, upon reasonably diligent investigation, the specifics of Merck's fraud until the public disclosure of the 2003 Harvard Study. Pet. App. 47a.

Affirmance on the investigation prong is all the more warranted given the posture of this case. The allegations in the Complaint note—in great detail—that until November 2004, Merck did not disclose its internal documents indicating that it knew of Vioxx's adverse cardiovascular side effects early on. A determination of whether, in the exercise of due diligence, such documents could have been discovered earlier without the assistance of compulsory discovery is properly a question for the finder of fact, and cannot be determined on a Rule 12(b)(6) motion to dismiss. See *Fujisawa*, 115 F.3d at 1335 (noting that access to relevant information is an important factor in "confirming or dispelling" the suspicions raised by inquiry notice).

CONCLUSION

For the above reasons, the Court should affirm the Third Circuit's decision.

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AMICUS CURIAE BRIEF

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Supreme Court of the United States

MERCK & CO., INC., *et al.*,

Petitioners,

v.

RICHARD REYNOLDS, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF THE PHARMACEUTICAL AND RESEARCH MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies.[1] PhRMA's members are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. New medicines account for 40 percent of the lifespan increase between 1986 and 2000, see Frank R. Lichtenberg, Nat'l Bureau of Econ. Research, Working Paper No. 9754, *The Impact of New Drug Launches on Longevity: Evidence From Longitudinal, Disease-Level Data From 52 Countries, 1982-2001*, at 21 (2003), and member companies are the source of a majority of all new medicines that have been discovered and marketed. PhRMA's members have invested approximately $300 billion in the last decade to develop new medicines – including over $50 billion last year alone. See PhRMA, *Pharmaceutical Industry Profile 2009*, at 32 (2009) ("Industry Profile"), *at* http://www.phrma.org/files/PhRMA2009 ProfileFINAL.pdf.

PhRMA members closely monitor legal issues that affect the industry, and PhRMA has frequently participated in cases before this Court raising such issues. See, *e.g.*, Brief for PhRMA and BIO as *Amici Curiae* Supporting Petitioner, *Wyeth* v. *Levine*, 129 S.

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[1] Each party has consented to the filing of this brief, and the parties' letters of consent have been lodged with the Clerk. Pursuant to Supreme Court Rule 37.6, no counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. A list of PhRMA's members is available at http://www.phrma.org.

Ct. 1187 (2009) (No. 06-1249); Brief for the Pharmaceutical Research and Manufacturers of America as *Amicus Curiae* Supporting Petitioners, *Warner-Lambert Co.* v. *Kent*, 128 S. Ct. 1168 (2008) (No. 06-1498); Brief of *Amicus Curiae* Pharmaceutical Research and Manufacturers of America in Support of Respondent, *eBay Inc.* v. *MercExchange, L.L.C.*, 547 U.S. 388 (2006) (No. 05-130).

The issue in this case is especially significant to PhRMA members because a number of them have borne the expense and burden of defending against securities-fraud class actions in recent years. In 2007 and 2008, for example, almost 50 such actions were filed against pharmaceutical and biotechnology companies. David A. Kotler, *Dechert Survey of Securities Fraud Class Actions Brought Against Life Sciences Companies* 2 (Apr. 2009) ("2009 Survey"), *at* http://www.dechert.com/library/Survey_of_Securities_Fraud_CA_4-09.pdf. Moreover, as explained in greater detail below, the nature of the industry makes pharmaceutical companies particularly likely to continue to be targets of securities-fraud strike suits in the future. These suits, which are often filed for their nuisance value, raise the already substantial costs and risks associated with the development of new medicines. Consequently, the approach taken by the Third Circuit, which makes it even more difficult for defendants to secure prompt dismissal of untimely nuisance claims at the pleadings stage, is of serious concern to PhRMA members.

SUMMARY OF ARGUMENT

1. The two-year statute of limitations set forth in 28 U.S.C. § 1658(b) should be construed to provide the certainty and predictability that this Court has repeatedly sought in securities-fraud litigation.

Recognizing the potential for abuse of securities-fraud class actions, this Court has rejected rules of liability that turn on fact-bound determinations and that offer little practical guidance. The need for certainty and predictability animated the Court's decision to adopt a uniform statute of limitations in *Lampf, Pleva, Lipkind, Prupis & Petigrow* v. *Gilbertson*, 501 U.S. 350 (1991), and these concerns apply equally to the interpretation of the limitations period later codified by Congress. The limitations defense, which is primarily designed to ensure fairness to defendants, is most useful when it establishes unambiguous, administrable rules that can be applied at the pleadings stage.

A certain and predictable limitations defense is vital to the pharmaceutical industry, whose members have regularly been targeted in securities-fraud strike suits. Already facing a lengthy and cumbersome regulatory-approval process, which precludes the release of most new drug prospects, developers of innovative medicines should not be saddled with the additional risk created by unworkable legal rules that give rise to costly civil discovery and uncertain litigation outcomes. This is especially true where, as here, a more administrable test is available and consistent with Congress's intent.

2. The certainty and predictability sought by the Court and pharmaceutical companies alike would be fostered by a rule under which the limitations period begins when the publicly available information would prompt a reasonable investor of ordinary intelligence to suspect that he has been defrauded. The standard can be met without information specifically suggesting scienter, because a material misstatement will almost invariably signal that something is amiss, that fraud is a possibility, and that the investor

should investigate further. Reasonable investors do not need to be hand-delivered direct evidence of fraud before they begin to suspect that a material misstatement might have been something more than an innocent mistake. Investors are not nearly so gullible as to warrant such a paternalistic approach.

Moreover, the test advocated by the government – which would delay the running of the limitations period until a hypothetical investor completed a hypothetical investigation and obtained enough information to survive a motion to dismiss – strays far from the certainty that a limitations defense demands, and should be rejected by this Court. The government's test would force courts to address hypothetical questions about the reasonableness of a plaintiff's investigation, a task that is even more speculative – and less likely to be resolved at the pleadings stage – when investors (like Respondents) do not conduct any investigation at all. In addition to these failings, the government's test leads to the untenable result that the limitations period begins to run only when the investor no longer needs to investigate because he already has all the information required to file a viable complaint. That result is not only counterintuitive; it is also contrary to the reason that Congress extended the limitations period in the first place: namely, to allow more time for an investigation.

ARGUMENT

I. SECTION 1658(B)'S LIMITATIONS PERIOD SHOULD BE CONSTRUED TO PROVIDE THE CERTAINTY AND PREDICTABILITY REQUIRED BY COMPANIES TARGETED IN SECURITIES-FRAUD SUITS.

A. This Court Has Consistently Sought To Prescribe Certain And Predictable Rules To Govern Securities-Fraud Litigation.

1. This Court has repeatedly stressed the need for unambiguous, readily administrable rules to govern and constrain private securities-fraud lawsuits. Without such rules, the Court has admonished, securities litigation can be employed "abusively to impose substantial costs on companies and individuals whose conduct conforms to the law." *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). "[P]laintiffs with weak claims [can] extort settlements from" companies that are innocent, but that nevertheless fear "extensive discovery and the potential for uncertainty and disruption in a lawsuit." *Stoneridge Invest. Partners, LLC* v. *Scientific-Atlanta, Inc.*, 128 S. Ct. 761, 772 (2008); see also *Merrill Lynch, Pierce, Fenner & Smith Inc.* v. *Dabit*, 547 U.S. 71, 80-81 (2006).

The risk that such suits will force settlements is anything but fanciful. In 2008 alone, almost 100 private securities suits settled for a total value of $3.6 billion. See PriceWaterhouseCoopers, *2008 Securities Litigation Study* 18 (Grace Lamont ed., 2009), *at* http://10b5.pwc.com/PDF/NY-09-0894SECURITIESLITSTUDYFINAL.PDF. That these cases sometimes settle for substantial amounts does not mean that the lawsuits are meritorious. To the contrary, and as this

Court acknowledged over 30 years ago, the staggering cost and disruption of the discovery process places immense pressure on companies to settle – regardless of the merits – once their motion to dismiss the suit on the pleadings has been denied. See *Blue Chip Stamps* v. *Manor Drug Stores*, 421 U.S. 723, 741 (1975); see also *Central Bank of Denver* v. *First Interstate Bank of Denver*, 511 U.S. 164, 189 (1994) ("uncertainty [in] the governing rules" could prompt companies, "as a business judgment, to abandon substantial defenses and to pay settlements in order to avoid the expense and risk of going to trial").

Given the high stakes involved, the risk of forced settlement, and the fact that the implied private right of action under § 10(b) of the Securities Exchange Act was judicially created out of whole cloth, the Court has not hesitated to consider "[t]he practical consequences" of interpreting securities-fraud liability expansively. See *Stoneridge*, 128 S. Ct. at 768-72. Litigation under § 10(b) and Rule 10b-5, the Court has consistently said, is "'an area that demands certainty and predictability.'" *Central Bank*, 511 U.S. at 188 (quoting *Pinter* v. *Dahl*, 486 U.S. 622, 652 (1988)). It is an "undesirable result" in such cases to announce rules affecting liability that will lead to judicial "decisions made on an ad hoc basis, offering little predictive value" to industry participants. *Id.* (internal quotation marks omitted).

The Court has thus rejected rules that could "throw open to the trier of fact many rather hazy issues of historical fact the proof of which depended almost entirely on oral testimony." *Blue Chip Stamps*, 421 U.S. at 743. The Court has likewise eschewed issuing "shifting and highly fact-oriented disposition[s]," which do not provide "a satisfactory basis for a rule of liability imposed on the conduct of business trans-

actions." *Central Bank*, 511 U.S. at 188 (internal quotation marks omitted). And, in implementing the substantive pleading standards that Congress crafted in 1995, the Court has sought to "prescribe a workable construction" that honors the legislature's "twin goals: to curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims." *Tellabs*, 551 U.S. at 322.

2. The same considerations favoring clear and administrable rules of liability apply with equal, if not greater, force to the statute of limitations that governs private securities-fraud suits under § 10(b). After all, like a rule limiting the scope of liability, the statute of limitations provides a dispositive defense that is available at the pleadings stage and that has the effect of a judgment on the merits. See *Plaut* v. *Spendthrift Farm, Inc.*, 514 U.S. 211, 228 (1995); *United States* v. *Oppenheimer*, 242 U.S. 85, 87-88 (1916); see also 18A Wright, Miller & Cooper, *Federal Practice and Procedure* § 4441, at 217 (2d ed. 2002) ("[A] limitations dismissal is a judgment on the merits that bars a second action on the same claim."). Moreover, if a securities-fraud defendant cannot rely on the limitations defense at the pleading stage due to a fact-bound, unpredictable rule, much of the value of the defense is lost. The defendant will be forced to incur the "substantial costs" of discovery, *Tellabs*, 551 U.S. at 313, or acquiesce in an "extort[ed] settlement[]," *Stoneridge*, 128 S. Ct. at 772.

Rules that are certain and predictable advance another "primar[y]" objective of statutes of limitations: "assur[ing] fairness to defendants." *Burnett* v. *New York Cent. R.R.*, 380 U.S. 424, 428 (1965). The "theory" underlying the limitations defense "is that even if one has a just claim it is unjust not to put the adversary on notice to defend within the period of

limitation and that the right to be free of stale claims in time comes to prevail over the right to prosecute them." *Order of R.R. Telegraphers* v. *Railway Express Agency*, 321 U.S. 342, 349 (1944) (Jackson, J.); *accord John R. Sand & Gravel Co.* v. *United States*, 128 S. Ct. 750, 753 (2008) ("[S]tatutes of limitations seek primarily to protect defendants against stale or unduly delayed claims.").

Limitations periods do more, however, than help defendants. They shield "the courts from having to deal with cases in which the search for truth may be seriously impaired by the loss of evidence, whether by death or disappearance of witnesses, fading memories, disappearance of documents, or otherwise." *United States* v. *Kubrick*, 444 U.S. 111, 117 (1979). And, they further important systemic interests in "repose . . . and *certainty* about a plaintiff's opportunity for recovery and a defendant's potential liabilities." *Rotella* v. *Wood*, 528 U.S. 549, 555 (2000) (emphasis added); see also S. Rep. No. 107-146, at 28 (2002) (additional views of eight Senators) (statutes of limitations in the securities area "provide for certainty in the markets").

Similar concerns over certainty and predictability animated this Court's decision to adopt the "uniform" statute of limitations that Congress later codified in § 1658(b). See *Lampf, Pleva, Lipkind, Prupis & Petigrow* v. *Gilbertson*, 501 U.S. 350, 357 (1991). In deviating from its practice of borrowing an analogous state limitations period when there is no express federal one, the Court in *Lampf* first considered "whether a uniform statute of limitations [wa]s to be selected." *Id.* The Court answered that question in the affirmative, concluding that "the federal interests in *predictability* and judicial economy counsel[ed]" in favor of a uniform rule in the context of claims under

§ 10(b) and Rule 10b-5. *Id.* (emphasis added). Federal law was better suited to provide that uniform rule, the Court explained, in part because the prospect of "multiple state limitations [periods] . . . would 'virtually guarante[e] . . . complex and expensive litigation over what should be a straightforward matter.'" *Id.* (second ellipsis and second alteration in original) (quoting *Agency Holding Corp.* v. *Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 154 (1987)). The limitations scheme selected by this Court and codified by Congress should thus be interpreted with the needs for predictability, certainty, and straightforward application as the primary bases for decision.

B. Certainty And Predictability In Securities-Fraud Litigation Is Especially Critical To Pharmaceutical Companies Forced To Defend Against Private Fraud Claims.

The need for certainty and predictability with respect to securities-fraud claims is particularly acute for companies in the pharmaceutical industry, where the road to success is long and expensive, and potentially crushing liability at the end of the road can be a powerful barrier to entry. Recent estimates place the average costs of developing and securing regulatory approval for each new drug at between $800 million and $1.3 billion. See Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* 2 (Oct. 2006) ("CBO Report"), *at* www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf.; Industry Profile at 38-39. From research and development to regulatory approval, moreover, the process takes approximately 12 years to complete, during which time the firm's capital is tied up and unavailable for other investments. CBO Report at 2; *see also* Industry Profile at 36 ("From the

first testing in the lab to FDA approval, the process takes an average of 10 to 15 years."). No return on that capital is earned unless and until the project succeeds – and even then, "just two in 10 medicines ever produce revenues that match or exceed average R&D costs." Industry Profile at 39. Overall, "[o]nly one of every 10,000 potential medicines investigated by America's research-based pharmaceutical companies makes it through the research and development pipeline and is approved for patient use by the United States Food and Drug Administration." PhRMA, *Innovation*, http://www.phrma.org/innovation/ (last visited Aug. 14, 2009).

In the face of these odds, legal rules that depend on highly fact-specific and *ad hoc* determinations only compound the uncertainty and costs to industry participants. At the margins, that uncertainty could tip the balance against a company pouring millions of dollars into attempting to develop the next innovation. Companies may be less likely to take the risk on a new treatment – like those that PhRMA members are currently developing for cancer, cardiovascular disease, and HIV/AIDS, see Industry Profile at 35 – when even an approved drug faces the continued uncertainty imposed by settlement-driven strike suits that cannot be dismissed on the pleadings and that can generate eight-figure legal bills. Cf. *Central Bank*, 511 U.S. at 188-89.

Many of the same characteristics that make it difficult to succeed in the pharmaceutical industry help explain why pharmaceutical companies are especially susceptible to securities-fraud nuisance suits. As noted, most new drugs do not produce a profit. And, each time the drug fails to match expectations, an enterprising plaintiffs' attorney will scour the record of all public statements in search of

anything that, in retrospect, may suggest the possibility of a misrepresentation. The attorney is aided by the lengthy regulatory-approval process, which requires generation and disclosure of information on the drug. The upshot is that each step in the process, and each set of disclosures, forces pharmaceutical companies to navigate a minefield: every positive report about a new drug can plant the seeds for a misrepresentation claim when results do not pan out as expected, and each decision not to reveal an arguable setback could lead to an allegation that the company unlawfully concealed negative material information.

The dilemma facing industry participants is evident from the lawsuits filed in recent years. Studies show that 10% of the more than 200 securities-fraud suits filed in 2008 were against life-sciences companies. *See* Kevin LaCroix, *A Closer Look at the 2008 Life Sciences Securities Lawsuits* (Feb. 3, 2009), *at* http://www.dandodiary.com/2009/02/articles/securities-litigation/a-closer-look-at-the-2008-life-sciences-securities-lawsuits/ (last visited Aug. 14, 2009). Although an increased number of suits attacked companies' accounting practices, the theory of liability in a quarter of the suits was that the defendant company made misleading statements about the safety of its product or concealed negative testing results. 2009 Survey at 2-3 & fig.2. As in this case, and of particular note, allegations of that sort have regularly followed on the heels of product-liability, consumer-fraud, and personal-injury suits against the same defendants.[2] The reality, then, is

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[2] Pet. App. 10a, 15a, 38a (decision below). *See also, e.g.*, *Masters* v. *GlaxoSmithKline*, 271 F. App'x 46 (2d Cir. 2008) (summary order); *In re Pfizer Inc. Sec. Litig.*, 584 F. Supp. 2d

that pharmaceutical companies releasing new medicines face the risk of multiple kinds of lawsuits, making it crucial to the company's planning that the limitations period for securities-fraud claims be predictable, that it encourage plaintiffs to bring suit promptly, and that it provide a meaningful defense on the pleadings should prospective plaintiffs fail to do so.

II. THE LIMITATIONS PERIOD SHOULD COMMENCE WHEN A REASONABLE INVESTOR OF ORDINARY INTELLIGENCE WOULD SUSPECT THAT HE HAS BEEN DEFRAUDED, AND SUCH SUSPICION DOES NOT REQUIRE INFORMATION SPECIFICALLY SUGGESTING SCIENTER.

1. As the case comes to this Court, three propositions are clear. First, a plaintiff need not have actual notice of the facts constituting the securities-fraud claim in order for the two-year limitations period to commence. Lower courts have unanimously held, and the parties agree, that constructive notice suffices. See Pet. Br. at 13, 18; Resp. BIO at 4-5, 15-16. Second, the constructive notice that triggers the statute of limitations is not knowledge of *all* of the facts underlying the alleged fraud, or even all of the facts needed to survive a motion for summary judgment. Instead, all sides agree that a lesser quantum of information will commence the running of the statute of limitations. Pet. Br. at 20-21; Resp. BIO at 15-16; Brief for the United States as *Amicus Curiae* at 7-8, *Trainer Wortham & Co.* v. *Betz*, No. 07-1489 (U.S. Apr. 22, 2009) ("U.S. Br."). Third, the starting point of the legal analysis is determining

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621 (S.D.N.Y. 2008); *In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496 (E.D.N.Y. 2008).

when the plaintiff was put on inquiry notice of the fraud. A plaintiff is on inquiry notice when the market receives "storm warnings"– *i.e.*, when the available information would prompt a reasonable investor of ordinary intelligence to suspect that he has been defrauded and prompt him to undertake an investigation. Pet. Br. at 20-21; Resp. BIO at 15-17; U.S. Br. at 8, 11.

What remains in dispute, then, is (i) whether information specifically suggesting scienter is necessary for a plaintiff to be on inquiry notice; and (ii) whether the investigation that a plaintiff undertakes (or could have undertaken) after receiving inquiry notice should postpone the running of the limitations period. *Amicus* respectfully submits that the Court should answer both questions in the negative. Information specifically relating to scienter is unnecessary, and the actual or hypothetical investigation does not toll the statute of limitations, which begins to run when the plaintiff receives inquiry notice.

a. As an initial matter, there is little support in law or logic for the notion that the suspicion of wrongdoing that triggers inquiry notice must include direct evidence confirming that the alleged mistake was fraudulent (rather than benign). "Commencement of a limitations period need not," as the Fourth Circuit has explained, "await the dawn of complete awareness." *Brumbaugh* v. *Princeton Partners*, 985 F.2d 157, 162 (4th Cir. 1993) (Wilkinson, J.); *accord Fujisawa Pharm. Co.* v. *Kapoor*, 115 F.3d 1332, 1334 (7th Cir. 1997) (rejecting contention "that the statute of limitations doesn't begin to run until the victim has in hand *all* the facts he needs in order to bring suit immediately"). "Inquiry notice is triggered by evidence of the possibility of fraud, not by complete

exposure of the alleged scam." *Brumbaugh*, 985 F.2d at 162; *Sterlin* v. *Biomune Sys.*, 154 F.3d 1191, 1203 (10th Cir. 1998) (same). As Petitioners have shown, it follows from this principle that information specifically supporting all elements of a securities-fraud claim – including evidence of scienter – is *not* a prerequisite to an investor's being on inquiry notice. Pet. Br. at 19-28.

This position makes eminent practical sense. After all, a material misstatement with consequences serious enough to warrant the filing of a federal lawsuit will almost invariably trigger at least a suspicion of fraud. Responsible investors are not Pollyannas. The disclosure should cause the investor's ears to perk up, suggesting that "'something may have been amiss'" and that the investor should inquire into the possible wrongdoing. See *Theoharous* v. *Fong*, 256 F.3d 1219, 1228 (11th Cir. 2001); see also *Rotella*, 528 U.S. at 555 (under discovery rule, "discovery of the injury, not discovery of the other elements of a claim, is what starts the clock"); *Wood* v. *Carpenter*, 101 U.S. 135, 141 (1879) ("'Whatever is notice enough to excite attention and put the party on his guard and call for inquiry, is notice of every thing to which such inquiry might have led. When a person has sufficient information to lead him to a fact, he shall be deemed conversant of it.'").

As Petitioners explain at greater length, this case is emblematic. Pet. Br. at 34-39. The FDA issued a warning letter, the contents of which previewed the theory that Respondents would advance in their complaint over two years later: "that the company and certain of its officers and directors intentionally misrepresented the cardiovascular safety of Vioxx and, consequently, the impact that Vioxx would have on Merck's financial health." Pet. App. 54a (Roth, J.,

dissenting). If (i) the detailed allegations in the FDA letter, (ii) the ensuing media coverage, (iii) the drop in stock price, and (iv) the product-liability and consumer-fraud suits filed against Merck did not suggest the possibility of fraudulent conduct and a need to investigate, see *id.* at 51a-59a, it is hard to see what, short of a public confession, would have.

Moreover, the standard proposed here provides a reasonable measure of the certainty that is a hallmark of a statute of limitations. See *Rotella*, 528 U.S. at 555. Inquiry notice in the form of "storm warnings" is, as a general matter, a point that courts can readily ascertain based on materials in the public domain. There is typically an identifiable point at which the misstatement was revealed to the market. That may be, as here, when reports are published in the mainstream media, see Pet. App. 88a-89a (reports in the New York Times, Wall Street Journal, USA Today, and Associated Press), or in press outlets specialized in business or industry news, *e.g.*, *Sterlin*, 154 F.3d at 1202-04 (article in business periodical). The misstatement could just as easily be revealed in court filings in other litigation. See *Masters* v. *GlaxoSmithKline*, 271 F. App'x 46, 49 (2d Cir. 2008) (suits under fraud and product-liability theories); *In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496, 536 (E.D.N.Y. 2008) (same); see also *Theoharous*, 256 F.3d at 1228 (bankruptcy filing). These sorts of identifiable points appear throughout the sizable body of case law on inquiry notice that the courts have developed over the last three decades, see *Cook* v. *Avien, Inc.*, 573 F.2d 685, 697 (1st Cir. 1978); Pet. Br. at 21; Resp. BIO at 15-16, which further suggests that the proposed standard will be the most easily administered.

b. The test proposed here also has the advantage of giving effect to Congress's expressed intent in enacting the two-year limitations period. Under this test, once the investor is on inquiry notice, he has a two-year window during which he may conduct an investigation and draft the complaint. See Pet. Br. at 14, 40. Indeed, the very reason that Congress extended the limitations period from one year to two was its belief that the one-year period adopted by the Court in *Lampf* did not provide sufficient time for an investor to "unravel" the fraud. See S. Rep. No. 107-146, at 9 (discussing "harsh" effects of one-year period). The purpose of the extra year, in other words, was to give the investor enough time to investigate. See also Pet. Br. at 32-33.

The alternative construction of the statute, which would toll the limitations period until a reasonable investor has completed his investigation, would render meaningless Congress's decision to extend the period to two years. The investor – together with his lawyer, who, in all likelihood, is the one who conducted the investigation – would have 730 days to do nothing but write a complaint. And it does not take two years to do that.

Amicus' proposed standard also has other virtues. First, it establishes an "objective" test consistent with what Congress had in mind when it enacted § 1658(b). See S. Rep. No. 107-146, at 29 (additional views of eight Senators) (legislation "not intended to change existing case law holding that an objective standard should be used to measure the starting point" of the limitations period). This objective test, in turn, promotes diligence by encouraging investors to "tak[e] the actions necessary to bring the fraud to light." *Brumbaugh*, 985 F.2d at 162. In so doing, the test helps to ensure that evidence presented on the

claim will be fresh, and that defendants will not be prejudiced by faded memories, absent witnesses, or lost documents. See *Rotella*, 528 U.S. at 559; *Kubrick*, 444 U.S. at 117; *Brumbaugh*, 985 F.2d at 162. Just as significant, the proposed test provides companies with a meaningful sense of repose within the five-year outer limit that Congress separately prescribed. See *Rotella*, 528 U.S. at 559; *Kubrick*, 444 U.S. at 117; *Brumbaugh*, 985 F.2d at 162. The objective standard, in sum, honors the balance that Congress has struck in reforming securities-fraud litigation over the past two decades: it requires plaintiffs to file suit soon after they are put on notice of their claims, but affords plaintiffs ample time to conduct the investigation. See *Sterlin*, 154 F.3d at 1203.

2. In its brief in a related case, the government has urged the Court to adopt a test that would toll the running of the statute of limitations until a hypothetical reasonable plaintiff completed a hypothetical investigation. Under that formulation, courts would first identify the point at which the investor had enough information to initiate an investigation into possible misconduct, and then "ascertain[] at what time the investor, in the exercise of reasonable diligence, should have discovered the facts constituting the alleged fraud." U.S. Br. at 8 (internal quotation marks omitted). The answer to the second question, the government submits, determines the start of the limitations period and is equivalent to the moment at which the investor would have enough information to plead a claim that could survive a motion to dismiss. *Id.* at 9. This Court should reject any such approach, which strays far from the certainty and predictability that securities litigation requires and which leads to a nonsensical result.

a. First, the government's test would create uncertainty by forcing courts to address a series of hypothetical questions that have no clear or easy answers. Such questions include:

- What information would an investor exercising "reasonable diligence" seek?
- What documents would he need to see?
- What individuals or institutions would he contact, and to whom would he speak?
- How long should a court assume it would take for any potential witnesses to return calls or otherwise respond to queries?
- How long should it take the investor to carry out all of these preliminary steps, as well as the follow-up needed to ensure that the contemplated fraud claim would not be frivolous?
- Keeping in mind the reality of the industry – in which lawyers often seek out investor plaintiffs, not vice versa – is the hypothetical investor represented by an attorney who can contribute resources to the investigation?

These questions are all the more difficult to answer where, as here, the investor-plaintiff has conducted no investigation whatsoever. Courts would in essence have to imagine a hypothetical investigation removed from any real-world actions that might serve as useful guideposts. See DRI Br. 14-18. This represents a far cry from the rule of predictable and "straightforward" application that this Court envisioned when adopting the limitations period in *Lampf*, 501 U.S. at 357. And, with some courts already hesitant to resolve an inquiry-notice dispute on the pleadings, *e.g.*, *LC Capital Partners, LP* v. *Frontier*

Ins. Group, Inc., 318 F.3d 148, 156 (2d Cir. 2003) (inquiry notice is an issue "often inappropriate for resolution on a motion to dismiss") (internal quotation marks omitted), the *ad hoc* determinations required by the government's rule would almost certainly get pushed back to the summary-judgment stage, if not further – after the defendant has borne the expense and disruption of civil discovery. By that point, many of the benefits of the limitations statute will have been lost, and the defendant often will have succumbed to the hydraulic pressure of protracted litigation and opted for settlement.

b. Even assuming that courts could easily resolve the kind of questions set forth above, which they likely could not, the view adopted by the government still suffers from a number of serious infirmities. Most evidently, the government's rule confuses the information that a plaintiff needs to have marshaled by the *end* of the two-year period with the information that will suffice to *trigger* the two-year period in the first place. This result makes no sense: the time to conduct an investigation begins to run only after the investor already has all the information he needs to survive a motion to dismiss, and thus no longer has any need to investigate. Under this view, the investor is given two years to draft a complaint – and, as discussed above, that is a task that takes days, not years, to complete. As Judge Posner aptly put it, "the potential plaintiff can complete his investigation, draft his complaint, and put the complaint in a drawer to be taken out in [two years] and filed if the price of the stock has fallen." *Fujisawa*, 115 F.3d at 1334.

c. The government's position also rests on the dubious premise that the limitations period should start running only when the plaintiff has enough

information to survive a motion to dismiss under the Private Securities Litigation Reform Act of 1995 ("PSLRA"). U.S. Br. at 9 & n.2. In support of this premise, the government not surprisingly cites no authority. Moreover, the government overlooks the fact that *Lampf* (which first established the limitations period) *predates* the PSLRA by four years. It is thus inconceivable that the Court intended to connect the limitations period with the not-yet-enacted PSLRA standard for surviving a motion to dismiss. Likewise, because Congress used the same language in § 1658(b) that this Court used in *Lampf*, changing only the length of the limitations and repose periods, there is no basis for concluding that Congress intended to toll the limitations period until the plaintiff has all the information necessary to survive a motion to dismiss. Cf. *Rotella*, 528 U.S. at 557 (rejecting trigger for limitations period that would dishonor legal rules "that Congress itself accepted and relied upon").

3. To the extent the Court is concerned that the objective standard proposed here would have the "harsh" effect of barring some potentially meritorious claims, that is "true in [the] case of any statute of limitations." See *Scaife Co.* v. *Comm'r*, 314 U.S. 459, 463 (1941); see also *Kubrick*, 444 U.S. at 117. But this Court has long recognized that fairness considerations of this sort, although possibly a basis for congressional intervention, "are not appropriate grounds for relief by the courts from the strictness of the statutory demand." *Scaife Co.*, 314 U.S. at 463.

"[R]elief by the courts" in this context would be especially misplaced for at least three reasons. First, securities-fraud plaintiffs are represented (and often sought out) by a sophisticated bar of specialized attorneys, see DRI Br. 25-28, such that they hardly

resemble the individual plaintiff doing his own legwork to take on a powerful corporation. Second, as a practical matter, all the plaintiff must do to satisfy the statute of limitations is file his complaint within the two-year window. Plaintiffs will generally be afforded ample opportunity to amend their complaints to incorporate any new information, see *Belizan* v. *Hershon*, 434 F.3d 579, 583-84 (D.C. Cir. 2006) (federal rule establishing liberal amendment policy not altered by PSLRA), and only after multiple amendments are complaints likely to be dismissed with prejudice. See, *e.g.*, Pet. App. 20a (fourth amended complaint). Finally, Congress has shown itself willing to extend the statute of limitations when it believes that victims of securities fraud are in fact being denied a suitable remedy. See S. Rep. No. 107-146, at 9. Congress of course remains free to reconsider the need for a longer limitations period for claims under § 10(b) and Rule 10b-5, including the option of a three-year period that was proposed but rejected in 2002. See S. Rep. No. 107-414, at 54 (2002) (minority views of five Senators).

CONCLUSION

For the foregoing reasons, and those stated in Petitioners' brief, the judgment of the Third Circuit should be reversed.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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Petitioners,

v.

RICHARD REYNOLDS, *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF THE SECURITIES INDUSTRY AND FINANCIAL MARKETS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

The Securities Industry and Financial Markets Association ("SIFMA") is a trade association that results from the November 1, 2006 merger of the Securities Industry Association and the Bond Market Association. It brings together the shared interests of more than 600 securities firms, banks, and asset managers that have a vital interest in the outcome of this appeal. SIFMA's mission is to promote policies and practices that expand and improve capital markets, foster the development of new products and services, and create efficiencies for member firms, while preserving and enhancing the public's trust and confidence in the industry and the markets. SIFMA works to represent its members' interests locally and globally through offices in New York, Washington, D.C., and London. Its associated firm, the Asia

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[1] The parties have consented to the filing of this brief. Petitioners and respondents have filed with the Clerk of the Court letters granting blanket consent to the filing of *amicus curiae* briefs.

Pursuant to Rule 37.6, *amicus curiae* affirms that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission. Willkie Farr & Gallagher LLP, counsel for *amicus curiae*, further states that it represents certain of the independent directors of the Board of Merck & Co., Inc. ("Merck") in other litigation concerning Merck, some of whom are also petitioners in this proceeding.

Securities Industry and Financial Markets Association, is based in Hong Kong. Unfortunately, SIFMA's members are often sued as defendants in class actions alleging violations of the Securities Exchange Act of 1934 ("1934 Act") and the Securities Act of 1933 ("1933 Act"). Thus, SIFMA is familiar with the everyday norms of securities litigation practices and, accordingly, the interactions between claims under the 1934 and 1933 Acts. This *amicus* brief focuses on those practices and interactions.

The question presented here—whether a plaintiff must be on inquiry notice of *scienter* before the statute of limitations set forth in 28 U.S.C. § 1658(b) begins to run in private securities fraud cases—is an issue of recurring importance to public companies, to the financial services industry, and to investors. All participants in the capital markets have a vital interest in ensuring that the standard for determining when the statute of limitations under § 1658(b) begins to run is clearly defined and that the application of that standard in real-world cases yields consistent, meaningful results. This brief makes two points. First, it describes clearly established law that a plaintiff who does not investigate does not get additional time for lack of notice. That proposition is sufficient to reverse the Third Circuit. Second, it focuses on four impractical and unworkable consequences that would flow if this Court were to endorse the Third Circuit's unduly narrow approach to this critical issue.

SUMMARY OF ARGUMENT

The federal securities laws protect defendants from having to defend against stale allegations of fraud by imposing a two-year statute of limitations for private claims brought under § 10(b) of the 1934 Act. 28 U.S.C. § 1658(b). The Circuits agree that the statute of limitations is triggered when the plaintiff has either actually or constructively discovered "the facts constituting the violation." They also agree that whether a plaintiff has constructive notice of such facts turns on whether the plaintiff received sufficient "storm warnings" of the alleged fraud such that a reasonable investor would have investigated further. But they do not agree on when the duty to inquire is triggered in § 10(b) cases. Section 1658(b) merely sought to provide plaintiffs an extra year in which to investigate a possible fraud; it did not seek to rewrite when inquiry notice begins.

Under the Third Circuit approach at issue in this case, no duty to inquire exists (and the statute of limitations does not begin to run) until investors receive sufficient storm warnings that defendants acted with *scienter* in perpetrating a fraud. *In re Merck & Co. Sec., Derivative & "ERISA" Litig.*, 543 F.3d 150, 172 (3d Cir. 2008). According to the Third Circuit, it would be unfair to start the statute of limitations running earlier because, under the PSLRA, plaintiffs are required to plead *scienter* with particularity. Under the Third Circuit's approach, therefore, plaintiffs are permitted to do nothing in

circumstances where they are already on notice of the possibility that defendants (intentionally or not) have misled them, until, *without* conducting an investigation, a hypothetical reasonable investor would have perceived evidence of *scienter*. As we explain below, a rule providing that the statute of limitations does not begin to run until a plaintiff passively receives evidence of *scienter* departs from settled principles of law and creates a number of unnecessary and intractable problems that Congress never intended and the law should not allow.

First, § 1658(b) did not, as respondents suggest, change the basic contours of when plaintiffs are on inquiry notice of a potential claim. Before § 1658(b) was enacted, the law was clear that inquiry notice was triggered by awareness of an injury, regardless of whether the plaintiff had knowledge of the defendant's culpability. The law was also clear that plaintiffs who failed to investigate following discovery of an injury would not be given additional time to bring claims. Thus, the Third Circuit erred in excusing respondents' failure to investigate and bring claims within two years of the alleged misstatement.

Second, the Third Circuit's approach is unrealistic and unworkable for four reasons.

i. The Third Circuit's approach ignores that plaintiffs, usually through class-action law firms, *already* conduct extensive pre-suit investigations before filing § 10(b) claims, and begin those

investigations as soon as misstatements are revealed. Lawyer-driven litigation remains the norm in the securities law arena. As lawyers, of course, plaintiffs' counsel know how to investigate; it is their stock in trade. But plaintiffs' counsel also have an additional incentive to ferret out potential fraud, "storm warnings" of *scienter* aside, because that is how they get clients and cases and, hence, how they get paid. Indeed, the promotional materials of class-action firms—including those firms representing the class here—trumpet their investigative abilities as a means of attracting clients. Moreover, plaintiffs' firms have commonly entered into "monitoring" arrangements with large investors, who are the most likely to be selected as lead plaintiffs in securities class actions pursuant to the PSLRA. *See, e.g., Iron Workers Local No. 25 Pension Fund v. Credit-Based Asset Servicing & Securitization, LLC*, 616 F. Supp. 2d 461, 464 (S.D.N.Y. 2009). The class-action law firms "monitor" the investment portfolios of potential lead plaintiffs—which often cover hundreds of securities—in exchange for a promise to be retained as counsel in the event the investor elects to sue. The proper application of when the "duty to inquire" begins for § 10(b) claims should reflect, not disregard, these everyday practices.

ii. The Third Circuit's approach—that there must be notice of *scienter* before the duty to inquire arises for *scienter*-based claims—would give rise to intractable problems in the application of the limitations period in a wide number of garden-variety

securities suits and lead to inconsistencies with other statutes of limitations under the federal securities laws. It is not uncommon, for example, for plaintiffs to assert claims under §§ 11 and 12 of the 1933 Act that "sound in fraud" and thus are subject to Federal Rule of Civil Procedure 9(b). Notice of *scienter* is not required in those cases before the limitations period begins to run. If it were, that would require courts to apply different limitation periods to the same claims depending on how the facts are pled. It is also not uncommon for 1933 Act and 1934 Act claims to be brought in the same suit based on the same alleged misrepresentations. Under the Third Circuit's approach, plaintiffs on constructive notice of a possible misrepresentation would be required to investigate for the purposes of their 1933 Act claims, but would not be required to investigate their 1934 Act claims until notice of *scienter* would have been discovered by the "hypothetical reasonable investor" without conducting an investigation. That plainly makes no sense as a practical matter and cannot be what Congress intended. A plaintiff already under a duty to investigate a potential misstatement should not be permitted to turn a blind eye to the possibility that the misstatement was intentionally made.

iii. The Third Circuit's approach is unworkable. Under the Third Circuit's approach, the determination of when plaintiffs should have been on inquiry notice of fraud is determined by analyzing when "the hypothetical reasonable investor" would have discovered and recognized storm warnings of

scienter, not on whether the actual plaintiff investigated and what it actually discovered. *Alaska Elec. Pension Fund v. Pharmacia Corp.*, 554 F.3d 342, 347 (3d Cir. 2009) (clarifying the standard introduced in this case). The Third Circuit's standard would require courts to engage in rank speculation about what such a "hypothetical investor" might have found depending on what the investor might have done. That is obviously unlikely to yield the consistency that the uniform application of the securities laws requires. *See Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 188 (1994) (§ 10(b) is "an area that demands certainty and predictability"). It also undermines the very purpose that securities claims limitations periods are meant to serve: to enable defendants to secure early dismissal of stale claims without undergoing the burden and expense that the defense of securities fraud claims notoriously entails.

iv. The Third Circuit's approach is unlimited and would have enormous ramifications for the doctrine of inquiry notice well beyond the § 10(b) context. According to the Third Circuit's rationale, the statute of limitations does not begin to run until a plaintiff is on inquiry notice of those facts it is required to plead in order to state a claim under § 10(b) because those facts must be pled with particularity under the PSLRA. Numerous other sorts of claims must also be supported by particularized allegations of fact, including all claims governed by the heightened pleading requirements of

Rule 9(b). Indeed, even under the notice pleading standard of Rule 8, every complaint must be supported by factual allegations that allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged, not facts that are merely consistent with a defendant's possible liability. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007); *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). If the statute of limitations is tied to requirements to plead facts, plaintiffs in all sorts of cases will be encouraged to pursue stale claims on the basis that they required more time to discover facts sufficient to meet whatever pleading standard applies.

Where (as here) a plaintiff has not conducted any investigation, no purpose would be served by extending the time within which to sue. Rather, it would run contrary to the clear purpose of the PSLRA to permit plaintiffs to excuse their failure to investigate and pursue their claims promptly until sufficient evidence of *scienter* fortuitously fell into their laps.

The proper standard should excuse a plaintiff's failure to file suit within two years of inquiry notice of the misrepresentation *only if* plaintiff pleads what investigatory steps it did take, what it discovered and when, and what specific facts enable it to plead *scienter* when it could not have before. The Third Circuit's decision should therefore be reversed.

ARGUMENT

I. THE THIRD CIRCUIT'S APPROACH DEPARTS FROM WELL-ESTABLISHED PRINCIPLES GOVERNING WHEN STATUTES OF LIMITATIONS BEGIN TO RUN.

Congress did not intend to "chang[e] the basic standards of the law" by enacting § 1658(b) in 2002. 148 Cong. Rec. 12,502 (2002) (statement of Sen. Leahy). Those "basic standards" support an interpretation of § 1658(b) under which the two-year limitations period for fraud claims begins to run from actual or constructive notice of the alleged misstatement, not from discovery of *scienter*, and is not extended for a plaintiff who fails to investigate.

a. It is undisputed that § 1658(b) incorporates the principle of inquiry notice. Before 2002, that principle had established that once a plaintiff becomes aware of certain information suggesting an event and injury, "the plaintiff should be on notice that further inquiry is needed" in order to pursue timely claims. 2 Calvin W. Corman, *Limitation of Actions* § 11.5.8, at 203 (1991).

b. Before § 1658(b) was enacted, the law was also clear that the information necessary to trigger inquiry notice was awareness of the event giving rise to the alleged injury—*not* awareness of the defendant's culpability. Two court of appeals

decisions that addressed this issue before § 1658(b) was enacted squarely held that the limitations period began running upon constructive notice of the alleged misstatement, without respect to *scienter*, *see Theoharous v. Fong*, 256 F.3d 1219, 1228 (11th Cir. 2001) and *Sterlin v. Biomune Systems*, 154 F.3d 1191, 1203 (10th Cir. 1998), while other court of appeals decisions made no mention of a *scienter* requirement for inquiry notice, *see Berry v. Valence Technology, Inc.*, 175 F.3d 699 (9th Cir. 1999) (collecting cases).

These cases were a logical outgrowth of the Supreme Court's interpretation of the concept of inquiry notice. In *United States v. Kubrick*, 444 U.S. 111, 116 (1979), the Court rejected a medical malpractice plaintiff's argument that the applicable statute of limitations under the Federal Tort Claims Act did not begin to run until the plaintiff had actual or constructive knowledge of negligence. The Court held that the limitations period began to run once the plaintiff should have discovered the "critical facts" of his injury, at which point he had to inquire to ascertain whether the treatment was negligent. *Id.* at 122. Recognizing that the plaintiff did not investigate following his injury, the Court went on to say that "[t]o excuse him from promptly doing so by postponing the accrual of his claim would undermine the purpose of the limitations statute, which is to require the reasonably diligent presentation of tort claims against the Government." *Id.* at 123.

Likewise, in *Rotella v. Wood*, 528 U.S. 549, 554 (2000), the Court rejected the proposition that the limitations period for civil RICO claims begins to run upon actual or constructive notice of both the injury and the pattern of racketeering. In doing so, the Court specifically considered and dismissed the argument that evidence of a pattern of racketeering was required to trigger the limitations period because that element must meet the heightened pleadings standard of Rule 9(b). *Id.* at 560-61. Thus, the Court explained that "in applying a discovery accrual rule, we have been at pains to explain that discovery of the injury, not discovery of the other elements of a claim, is what starts the clock." *Id.* at 555; *see also Wood v. Carpenter*, 101 U.S. 135, 141 (1879) ("[W]hatever is notice enough to excite attention and put the party on his guard and call for inquiry, is notice of every thing to which such inquiry might have led." (quoting *Kennedy v. Green*, 3 Myl & K. 699, 722, 40 Eng. Rep. 266, 275 (Ch. 1834) (opinion of Lord Brougham))).

As these cases demonstrate, at the time § 1658(b) was enacted, inquiry notice in the securities law context and other contexts was triggered by notice of the alleged event causing injury, regardless of notice of the other elements of the claim at issue. Section 1658(b) was not designed to "chang[e] the basic standards of law" in this area. 148 Cong. Rec. 12,502. Rather, as the Senate Judiciary Committee report explained, § 1658(b) was simply designed to give plaintiffs an extra year from discovery of a misstatement to investigate before being required to

plead fraud with the particularity required by the PSLRA:

> The one year statute of limitations from the date the fraud is discovered is also particularly harsh on innocent defrauded investors. . . . Especially in securities fraud cases, the complexities of how the fraud was executed often take well over a year to unravel, even after the fraud is discovered.
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> * * *
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> With the higher pleading standards that . . . govern securities fraud victims, it is unfair to expect victims to be able to negotiate such obstacles in the span of 12 months.

S. Rep. No. 107-146, at 9 (2002). Congress did not, as respondents suggest, seek to give plaintiffs an extra year *plus* a radical alteration of the judicially established trigger for inquiry notice.

c. It was also well established before 2002 that plaintiffs who failed to investigate would not be allowed additional time to sue under an inquiry notice rule. *See United States v. Diamond Coal & Coke Co.*, 255 U.S. 323, 333 (1921) (where a plaintiff "fail[s] to make inquiry," the plaintiff is not entitled to the discovery rule); *see also Kubrick*, 444 U.S. at 123 (refusing to excuse plaintiff's failure to investigate).

That legal rule is dispositive here because respondents concede they did not undertake any investigation into the matters asserted in their complaint. *See, e.g.*, Pet. App. 58a (Roth, J., dissenting); *id.* at 98a (district court); *cf.* C.A. App. 5032-5033 (statement of Melvyn Weiss) (conceding, in response to the district court's question as to whether "you" or "your client" conducted an investigation, that "we didn't do it ourselves").

Thus, the Third Circuit erred in granting respondents more than two years to sue when they failed to investigate upon discovering the alleged misstatements. If this Court were to uphold the Third Circuit's decision, it would depart from its settled approach to inquiry notice and read into § 1658(b) a change in the law that Congress did not intend.

II. THE THIRD CIRCUIT'S APPROACH IS IMPRACTICAL AND UNWORKABLE.

A. The Proper Inquiry Notice Standard Should Reflect The Practical Reality That Plaintiffs' Lawyers Already Conduct Extensive Investigations Before Passively Receiving Evidence Of *Scienter*.

The Court has sought to interpret the securities laws in a manner consistent with economic reality. *See, e.g.*, *Reves v. Ernst & Young*, 494 U.S.

56, 61 (1990) (interpreting what constitutes a "security" based on "economic reality"). The Court's interpretation of what constitutes inquiry notice sufficient to trigger the statute of limitations for § 10(b) claims, as set forth in § 1658(b), should similarly reflect economic reality. As reflected in its opinion, the Third Circuit apparently believed that it would be unfair to burden § 10(b) plaintiffs with any investigatory obligations absent "storm warnings" of each element of a § 10(b) claim. The reality is, however, that the driving force behind § 10(b) class actions is plaintiffs' lawyers (not investors) who *already* conduct extensive investigations of potential securities fraud claims as soon as misstatements are discovered because (a) that is what they are trained to do, (b) that is what the rules require them to do, and (c) they have enormous economic incentives to do so.

Despite the PSLRA, it remains the norm that securities class-action litigation is lawyer-driven, no doubt because the potential for huge fees remains as alluring as ever. *See* Stephen J. Choi & Robert B. Thompson, *Securities Litigation and Its Lawyers: Changes During the First Decade After the PSLRA*, 106 Colum. L. Rev. 1489, 1496 (2006) (noting, of the first decade since the PSLRA's enactment: "If anything, it is more likely that litigation has gone up rather than gone down over the entire period."); *Iron Workers*, 616 F. Supp. 2d at 463 (noting that "increased legal fees" continue to drive plaintiffs' firms to vie for lead counsel status in large securities suits). In 2008 there was an "unprecedented" amount

of securities litigation against firms in the financial industry "since the passage of the [PSLRA]," Cornerstone Research, *Securities Class Action Filings, 2008: A Year in Review* 2 (2009), http://securities.cornerstone.com/pdfs/YIR2008.pdf, and the wave of litigation against that sector continues to build this year, Stephanie Plancich & Svetlana Starykh, NERA, *Recent Trends in Securities Class Action Litigation: 2009 Mid-Year Update* 5 (July 2009), http://www.nera.com/image/Recent_Trends_Report_0709.pdf. From 1998 to 2008, securities class actions resulted in $51.8 billion of settlements. U.S. Chamber Institute for Legal Reform, *Securities Class Action Litigation, The Problem, Its Impact, and the Path to Reform* 8 (July 2008), http://www.instituteforlegalreform.com/get_ilr_doc.php?docId=1213. Accordingly, plaintiffs' lawyers, who typically collect one-third of a settlement, reaped an estimated $17 billion in fees over that same period. *Id.* at 19. The average value of settlements so far in 2009 is at an all-time high (excluding settlements over $1 billion). Plancich & Starykh, *supra* at 22-23. An analysis of current trends predicts that securities class-action settlement amounts will continue to increase in the future. Ellen M. Ryan & Lauren E. Simmons, Cornerstone Research, *Securities Class Action Settlements 2008 Review and Analysis* 19 (2009), http://securities.cornerstone.com/pdfs/Cornerstone_Research_Settlements_2008_Analysis.pdf.

Perhaps most astonishing of all, one study found that even after the PSLRA, and *before* the

current economic crisis, more than 40% of companies listed on major U.S. exchanges had been named as defendants in securities fraud class actions. Comm'n on the Regulation of U.S. Capital Mkts. in the 21st Century, *Report and Recommendations* 30 (Mar. 2007), http://www.uschamber.com/publications/reports/0703capmarketscomm.htm. Plainly, the PSLRA has not dampened the ardor of securities class-action counsel to bring lawsuits.

The economic reality is that plaintiffs' firms *already* conduct extensive pre-suit investigations before evidence of *scienter* falls in their laps. The marketing materials of class-action firms trumpet the abilities of the plaintiffs' bar to ferret out corporate wrongdoing. For instance, the website for co-lead plaintiffs' counsel in this case states, "In order to help institutional funds properly track potential securities frauds and recoup losses, BLB&G employs a state-of-the-art proprietary portfolio monitoring and case evaluation system." Bernstein, Litowitz, Berger & Grossman LLP, Institutional Investor Services, http://www.blbglaw.com/institutional_investor_services/index. The website goes on to explain that the firm "review[s] the fund's portfolio losses on a regular basis, *investigate[s] potential claims* and prepare[s] detailed reports of [its] findings." *Id.*, http://www.blbglaw.com/institutional_investor_services/portfolio_monitoring (emphasis added). Similarly, the website for the other co-lead plaintiffs' counsel below touts portfolio monitoring and investigatory capabilities that enable the firm "to alert its clients in

a prompt manner that their investments have been harmed *by fraud* or other corporate misconduct." Brower Piven, http://www.browerpiven.com/institutionalinvestors.html (emphasis added). That same website also contains a "Report Fraud" feature that solicits evidence of fraud from corporate insiders and others to aid investigations into whether a misstatement or omission was fraudulent. *Id.*, http://browerpiven.com/reportfraud.html.

Indeed, a number of recent cases have brought to light certain arrangements that members of the plaintiffs' bar have developed to secure the appointment of their clients as lead plaintiffs in securities fraud class actions (and thus substantial fees for the law firms). Under these arrangements, known as "monitoring" arrangements, plaintiffs' firms agree to provide free "monitoring" of the portfolios of large institutional investors (*i.e.*, potential lead plaintiffs) in exchange for the right to be retained as counsel if the investor decides to bring a lawsuit upon detection of purported fraud or other irregularities. *See, e.g.*, *Iron Workers*, 616 F. Supp. 2d at 464 (monitoring arrangement between major plaintiffs' firm and a large pension fund); *Adams v. Labaton, Sucharow & Rudoff LLP*, No. 07-7017, 2009 U.S. Dist. LEXIS 35085, at *5-6 (S.D.N.Y. Mar. 30, 2009) (monitoring arrangements with the State of New Mexico); *In re JP Morgan Chase & Co. S'holder Derivative Litig.*, 08-974, 2008 U.S. Dist. LEXIS 71353, at *29 (S.D.N.Y. Sept. 19, 2008) (monitoring arrangements with "professional plaintiff" that

resulted "in at least twenty-five cases to date"); *In re Am. Italian Pasta Co. Sec. Litig.*, No. 05-725, 2007 U.S. Dist. LEXIS 21365, at *21 (W.D. Mo. Mar. 26, 2007) (monitoring arrangement with a large pension fund).

There can be no serious dispute, therefore, that imposing a duty to inquire when a misstatement is discovered, but before evidence of *scienter* is passively received, would not impose a new and burdensome duty. On the contrary, it would merely recognize what is already the established practice.

B. The Third Circuit's Approach Would Lead To Inconsistencies With The Application Of Other Statutes Of Limitations Under The Federal Securities Laws.

As the Court in *Lampf, Pleva, Lipkind, Prupis & Pettigrow v. Gilbertson*, 501 U.S. 350, 360 (1991), held, the statute of limitations for § 10(b) should be interpreted so as to ensure that "the complex web of regulations" in the 1933 and 1934 Acts achieves its "central goal." That goal would be undermined if the Third Circuit's approach of tethering statutes of limitations to pleading standards were to be adopted.

1. The Third Circuit's Approach Would Create Conflict And Confusion With Respect To The Limitations Period Applicable To 1933 Act Claims That "Sound In Fraud" Or Are Based On Opinions.

Claims under the 1933 Act, including the oft-asserted §§ 11 and 12 claims, are subject to that Act's one-year limitations provision, which is set forth in § 13. 15 U.S.C. § 77m. The one-year limitations period for 1933 Act claims begins to run once plaintiffs knew or should have known of the alleged misstatement or omission, regardless of defendant's intent. *Id.*; *In re Alstom SA, Sec. Litig.*, 406 F. Supp. 2d 402, 417 (S.D.N.Y. 2005).

Although *scienter* is not a necessary element of all claims under §§ 11 and 12, it can be where plaintiffs assert a 1933 Act claim that "sounds in fraud." For example, §§ 11 and 12 claims that are based on allegedly false *opinions* require proof that "the opinion or belief [was] not truly held" because the speaker's belief is the only fact that is represented. *In re Global Crossing Ltd. Sec. Litig.*, 313 F. Supp. 2d 189, 210-11 (S.D.N.Y. 2003); *see also Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1095-96 (1991) (securities claim premised on opinion requires, in addition to objective unreasonableness, that the speaker misstated "the psychological fact of the speaker's belief in what he says"). These kinds of

§§ 11 and 12 claims are especially common in the wake of the current economic crisis, with companies increasingly being attacked for matters of opinion concerning valuations (*e.g.*, judgment-driven valuations about illiquid securities) or forward-looking projections (*e.g.*, statements about how a company expects to perform at a later date). *See Securities Class Action Filings, 2008* at 21 (noting that "[t]he share of class actions alleging Section 11 and 12(2) claims increased to its highest level in 2008," and many such claims were premised on "overstatements of assets" and "problems with estimates"). Another example of §§ 11 and 12 claims sounding in fraud are those based on forward-looking statements. Under the PSLRA, forward-looking statements are not actionable unless they are made with "actual knowledge . . . that the statement was false or misleading." 15 U.S.C. § 77z-2(c)(1)(B)(i). And similarly, "control person" claims under § 15 of the 1933 Act can be asserted only against defendants who are "culpable participants in the fraud perpetuated by the controlled persons." *Lanza v. Drexel & Co.*, 479 F.2d 1277, 1299 (2d Cir. 1973); *Wallace v. Buttar*, 239 F. Supp. 2d 388, 397 (S.D.N.Y. 2003) ("the control person must have participated in the action with knowledge that the securities laws were being violated, or with reckless indifference as to whether a violation occurred"), *rev'd on other grounds*, 378 F.3d 182 (2d Cir. 2004).

Thus, certain claims brought under those sections must satisfy heightened pleading

requirements that are similar to those imposed by the PSLRA with respect to § 10(b) claims. Specifically, §§ 11 and 12 claims that "sound in fraud" must be pled with the particularity required by Rule 9(b). *See, e.g.*, *Rombach v. Chang*, 355 F.3d 164, 171 (2d Cir. 2004) ("So while a plaintiff need allege no more than negligence to proceed under Section 11 and Section 12(a)(2), claims that do rely upon averments of fraud are subject to the test of Rule 9(b).").

If the Third Circuit is correct that inquiry notice of fraud claims requires a reason to suspect *scienter* when claims sound in fraud and are subject to a heightened pleading requirement, then logically the limitations period under § 13 would begin to run later for §§ 11 and 12 claims that "sound in fraud" than for those that do not. But § 13 provides for a limitations period of one year after inquiry notice of a misstatement or omission for *all* 1933 Act claims—whether based on false statements of fact, false opinions, forward-looking statements, or control person allegations. 15 U.S.C. § 77(m).

The Third Circuit's premise that there should be a different statute of limitations for securities claims that sound in fraud is contradicted by Congress's choice of a unitary statute of limitations in § 13. To hold otherwise would result in an interpretation of § 13 that creates different limitations periods for §§ 11 or 12 claims depending on how they are pled. Such an interpretation is an invitation for mischief. It would encourage plaintiffs

to engage in artful pleading of §§ 11 and 12 claims in order to avail themselves of a longer limitations period than what § 13 intended. Indeed, one lower court that addressed precisely this issue recognized as much:

> [T]he adoption of the Plaintiffs' position—that a longer limitations period should be applied when a complaint's Section 11 or 12(a)(2) claims "sound in fraud," but that a shorter period is applicable where the claims only raise allegations of negligence—creates uncertainty in an area of the law the purpose of which is expressly to provide certainty for defendants as to when their exposure to liability ends.

Alstom, 406 F. Supp. 2d at 417 (holding that the longer fraud limitations period of § 1658(b) did not apply to §§ 11 and 12 claims "sounding in fraud").

The alternative approach urged here would avoid such problems without depriving plaintiffs of meritorious fraud claims. That is because inquiry notice would run on a uniform basis, without respect to evidence of *scienter*, for all securities claims, and plaintiffs could avoid having their fraud claims time-barred if they could prove that evidence of *scienter* became reasonably available only through an actual investigation conducted after the duty to inquire was triggered by notice of a false statement or omission.

2. The Third Circuit's Approach Would Nonsensically Require Plaintiffs To Investigate A Misrepresentation But Inquire No Further As To The Possibility Of Fraud.

It would make no sense to hold that the limitations periods for related claims asserted under different provisions of the securities laws based on the same set of facts run from different points in time. As a practical matter, the Third Circuit's approach would require the same plaintiffs to investigate a purported misrepresentation for purposes of potential claims pursuant to the 1933 Act, but go no further and inquire as to whether the misrepresentation was fraudulent for a potential § 10(b) claim. *See, e.g., In re Flag Telecom Holdings, Ltd. Sec. Litig.*, ___ F.3d ___, Nos. 07-4017, 07-4025, 2009 WL 2169197, at *6 (2d Cir. July 22, 2009) (class actions asserting both 1933 and 1934 Act claims "are far from unusual") (citing cases). The entire reason Congress extended the statute of limitations for fraud from one to two years was to give plaintiffs one more year following discovery of a misrepresentation to amass the evidence necessary to plead and prove all of the elements, including *scienter*, of a § 10(b) claim. The Third Circuit has essentially rewritten the statute to allow plaintiffs alleging fraud an additional year *plus* some additional uncertain period before inquiry

notice is triggered to be adjudicated in each § 10(b) case.

3. The Third Circuit's Approach Would Encourage Plaintiffs To Dress Up Stale 1933 Act Claims As Fraud Claims.

The Third Circuit's *scienter*-based distinction as to when the limitations period for fraud claims begins to run creates even more incentive on the part of securities plaintiffs and their counsel to dress up time-barred 1933 Act claims as § 10(b) fraud claims. This is because plaintiffs barred from bringing claims under §§ 11 and 12 for a misstatement that was or should have been discovered more than a year ago would seek to recast those claims as § 10(b) fraud claims subject to the longer two-year limitations period that did not begin running until they passively received evidence of *scienter*. The Court should not adopt a rule that encourages an end-run around the time limit imposed by Congress on §§ 11 and 12 claims. *See, e.g.*, *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 210 (1976) (rejecting interpretations of § 10(b) that would "nullify the effectiveness of the carefully drawn procedural restrictions on th[e] express actions" in §§ 11 and 12).

C. The Third Circuit's Approach Is Unworkable.

According to the Third Circuit, inquiry notice of *scienter* is necessary to give investors additional time to investigate their claims so as to meet the heightened pleading standards of the PSLRA. Where, however, a plaintiff has not conducted any investigation (as was the case here), no purpose would be served by extending the time within which to sue beyond two years from inquiry notice that there was a misrepresentation. Rather, it would run contrary to the clear purpose of the PSLRA to permit plaintiffs to excuse their failure to investigate and pursue their claims promptly simply because a "hypothetical" investor conducting a "hypothetical" investigation would not have uncovered facts sufficient to support an inference of *scienter*. The Third Circuit's standard is unworkable because it requires courts to engage in speculation at each and every step of that purported standard in order to determine whether or not a claim is time-barred.

First, the court must speculate as to what type of information would constitute evidence of *scienter* sufficient to place a hypothetical investor on notice of a possible fraud. Short of an admission of wrongdoing—*e.g.*, a guilty plea to criminal securities fraud with respect to the same misrepresentations that are alleged in a class-action plaintiff's complaint—it is hard to imagine what "storm warnings" of *scienter* could possibly suffice. Indeed,

even readily available information, such as an insider's trading activity, may not be viewed by reasonable investors in the same way. Some investors might consider stock sales by senior management shortly before their company made purported misstatements as evidence of *scienter*, whereas others might overlook such a fact or discount it because they also discovered the sales were made automatically for estate planning, tax purposes, or the like. *See, e.g., In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004) (trades by insiders "to pay taxes" do not support *scienter*).

Second, the court will need to speculate on what type of reasonable investigation a hypothetical plaintiff would have conducted in an effort to uncover evidence of *scienter*. In such a process, the court would engage in pure conjecture as to how a hypothetical investor would have proceeded with that investigation upon discovery of each piece of evidence that the court speculates he or she would have learned during that hypothetical investigation.

Third, based on its supposition as to the steps that the hypothetical investigation would have involved, the court must further speculate as to both (i) what pieces of evidence that investor would have discovered with regard to *scienter*, and (ii) the precise day on which that investor would have learned each and every one of those pieces of evidence. The court must engage in both levels of speculation in order to determine whether that evidence, overall, is enough

to put a hypothetical investor on inquiry notice of a § 10(b) claim and, if so, the exact date on which the hypothetical investor would have uncovered sufficient evidence to cause the statute of limitations to begin to run. This would result in massive confusion and uncertainty for courts and litigants alike.

The uncertainty that results from the hypothetical investor test is contrary to this Court's admonition. As the Court has long recognized, unchecked § 10(b) litigation "presents a danger of vexatiousness different in degree and in kind from that which accompanies litigation in general." *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 739 (1975). Without clear, consistent standards, decisions are "'made on an ad hoc basis, offering little predictive value' to those who provide services to participants in the securities business." *Cent. Bank*, 511 U.S. at 188 (quoting *Pinter v. Dahl*, 486 U.S. 622, 652 (1988)). This uncertainty only increases the *in terrorem* effect inherent in securities fraud class actions that lends them "a settlement value to the plaintiff out of any proportion to its prospect of success at trial." *Blue Chip Stamps*, 421 U.S. at 740.

The uncertainty would make access to the U.S. capital markets more expensive as companies would have to accrue for potential litigation over longer periods of time and litigate stale lawsuits with substantial discovery expense. In comparison, foreign markets—which limit or prohibit private class actions—would become more attractive to both U.S.

and foreign companies, depriving U.S. investors of bona fide investment opportunities. *See* H.R. Rep. No. 104-50, at 20 (1995) ("Fear of [securities] litigation keeps companies out of the capital markets."). Consequently, private securities litigation would continue to undermine the competitive footing of the U.S. capital markets. *See* Interim Report of the Comm. on Capital Mkts. Regulation at 11 (2006), *available at* http://www.capmktsreg.org/pdfs/11.30Committee_Interim_ReportREV2.pdf ("Foreign companies commonly cite the U.S. class action enforcement system as the most important reason why they do not want to list in the U.S. market."). Former Treasury Secretary Paulson crystallized the relevant policy concerns as follows: "Our markets are, indeed, the best in the world. Yet we must be vigilant, and we must do everything we can to ensure they stay that way. . . . [T]he fundamental question we must ask is: Have we struck the right balance between investor protection and market competitiveness . . . ?" Henry M. Paulson, Jr., Opening Remarks at Treasury's Capital Markets Competitiveness Conference (Mar. 13, 2007), http://www.ustreas.gov/press/releases/hp306.htm. The Third Circuit's approach upsets the right balance.

Consider, for example, a public company that announces it is undertaking an internal investigation into potential securities fraud. Even after arriving at a conclusion that no fraud had occurred, the company could not take any comfort in concluding that the

clock was running on a potential § 10(b) claim because plaintiffs and courts may disagree over what a hypothetical investor should have done in response to that news. Some courts might hold that the hypothetical investor still had no evidence of *scienter*, and therefore the limitations period had not begun. Other courts might hold otherwise. Companies, and their ability to conduct business competitively, would be caught in limbo.

Instead, if plaintiffs wish to excuse their failure to file suit earlier, they should be required to plead the steps they did take, what they discovered and when, and why specific newly discovered facts enabled plaintiffs to plead *scienter* that could not have been alleged before, consistent with Rule 11 and the PSLRA. *See, e.g.*, *Wood* 101 U.S. at 143 ("The circumstances of the discovery must be fully stated and proved, and the delay which has occurred must be shown to be consistent with the requisite diligence."); *Del Campo v. Camarillo*, 98 P. 1049, 1054 (Cal. 1908) (plaintiffs "must clearly show that they did not discover the existence or commission of the alleged frauds until within a reasonable time before the action was begun, that they proceeded promptly upon such discovery, and that their failure to make the discovery sooner was not due to their own lack of diligence"). This approach would give the lower courts an objective basis for evaluating whether pleading a complaint for securities fraud was truly beyond plaintiffs' reach. Applying this approach to the example above, courts could easily and objectively

evaluate whether a plaintiff seeking to assert a timely fraud claim in the wake of a corporate internal investigation conducted a diligent investigation but could not find evidence of *scienter* within the two-year limitations period.

D. The Third Circuit's Approach Would Affect The Statutes Of Limitations Applicable To Virtually Any Claim That Is Filed In Federal Court.

The expansive principle behind the inquiry notice rule adopted by the Third Circuit could not be limited to § 10(b) claims or even to those arising under the federal securities laws. Rather, by linking the quantum of information necessary to trigger the duty to inquire to the specific pleading requirements applicable to § 10(b) claims under the PSLRA, the rule adopted by the Third Circuit would affect statutes of limitations based on discovery for numerous claims that must be supported by allegations of fact.

For example, any plaintiff who "alleg[es] fraud or mistake . . . must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Under the rule adopted by the Third Circuit, therefore, a plaintiff alleging a claim that sounds in fraud—whether based on the securities laws or otherwise—would be under no duty to inquire into whether it has a potential claim until storm

warnings of all the circumstances constituting the fraud, including *scienter*, fell into its lap.

The limitations period would also be extended for claims not subject to the heightened pleading standards for fraud. As *Twombly* and *Iqbal* make clear, to state a claim for relief under Rule 8, a complaint must "plead[] *factual content* that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S. Ct. at 1949 (emphasis added). A complaint that "pleads facts that are 'merely consistent with' a defendant's liability" is insufficient, because "it 'stops short of the line between possibility and plausibility of 'entitlement to relief.'"") *Id.* (quoting *Twombly*, 550 U.S. at 557). Thus, even in cases governed by the notice pleading standard of Rule 8, the Third Circuit's test would relieve a plaintiff of any duty to investigate a potential claim (and effectively toll the statute of limitations from running) until it passively received *all* the necessary facts that, if proven true, would render that claim plausible.

Extending a statute of limitations based on pleading standards is thus a proposition without limit and will invite litigation and mischief in any case to which the inquiry notice doctrine applies. Plaintiffs in all sorts of cases will be encouraged to pursue stale claims on the grounds that they lacked notice of the facts necessary to state a claim, stripping the duty to inquire of any real meaning and depriving defendants

and our crowded courts of the protections that the statute of limitations were meant to provide.

CONCLUSION

For the reasons stated, the Third Circuit's decision should be reversed.

Respectfully submitted,

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August 2009

AMICUS CURIAE BRIEF

(11)

No. 08-905

IN THE

Supreme Court of the United States

MERCK & CO., INC., ET AL.,

Petitioners,

v.

RICHARD REYNOLDS, ET AL.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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INTEREST OF THE AMICUS CURIAE[1]

The Washington Legal Foundation ("WLF") is a national, non-profit public interest law and policy center based in Washington, D.C., with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, business civil liberties, and a limited and accountable government. To that end, WLF has appeared before this Court and other federal and state courts as *amicus curiae* in numerous cases raising issues relating to the proper scope of the federal securities laws, *see, e.g.*, *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007); *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71 (2006); *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336 (2005), and to the appropriate interpretation of the statute of limitations in private actions, *see, e.g.*, *Klehr v. A.O. Smith Corp.*, 521 U.S. 179 (1997); *Rotella v. Wood*, 528 U.S. 549 (2000). WLF has no financial interest in the outcome of this case.

The question presented here concerns a legal issue of fundamental importance to the financial industry, investors, and the national economy. WLF has a vital interest in ensuring that the uniform standards for the limitations periods for securities fraud claims adopted by Congress to curb abuse of the federal securities laws are not undermined. The

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[1] Letters from the parties consenting to the filing of all amicus briefs have been filed with the Clerk of the Court. No counsel for any party to these proceedings authored this brief, in whole or in part. No other entity or person, aside from *amicus* WLF and its counsel made any monetary contribution for the preparation or submission of this brief.

Court should not adopt an interpretation that effectively nullifies the time limit set under the discovery rule established by Congress in the Sarbanes-Oxley Act of 2002 and by this Court's decision in *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991).

Because plaintiffs generally have substantial discretion in choosing the forum when bringing suits involving nationally traded securities, WLF is concerned that the Third Circuit's decision opens a window for opportunistic plaintiffs to bring stale securities law claims, contrary to the express limits set by Congress and applied by other courts of appeals around the country. The Third Circuit's decision would raise the costs of capital for public companies and would negatively impact the effective functioning of the American economy. As *amicus curiae*, WLF believes that this brief presents relevant matter concerning the history of inquiry notice that has not previously been brought to the Court's attention by the parties and that may assist the Court in determining and resolving the issues presented.

SUMMARY OF ARGUMENT

In *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991), this Court held that the judicially inferred cause of action under section 10(b) of the Securities and Exchange Act of 1934 is subject to a two-tiered limitations period, parallel to the express statutes of limitations that Congress had established elsewhere under the Act. Borrowing from section 9(e) of the 1934 Act, the Court concluded that section 10(b) actions must be "brought within one year after the discovery of the facts con-

stituting the violation and within three years after such violation." 501 U.S. at 360 n.6 (quoting 15 U.S.C. § 78i(e)). Congress ratified the two-tiered structure in the Sarbanes-Oxley Act of 2002, which extended the respective limitations periods to two years after discovery and five years after the violation itself. *See* 28 U.S.C. § 1658(b).

Following *Lampf*, the courts of appeals have reached general agreement over several principles underlying what constitutes the "discovery of the facts constituting the violation." All of the circuits recognize that the statute of limitations begins to run not just from the actual discovery of the facts, but from their constructive discovery, the point at which the investor, in the exercise of reasonable diligence, should have discovered the facts. In addition, the circuits have agreed that the investor's obligation to exercise reasonable diligence incorporates the doctrine of "inquiry notice," requiring an investor, upon perceiving sufficient facts to raise a suspicion, to conduct a further investigation into the underlying claims.

Although the circuits have agreed on the basic framework under the 1934 Act, they have disagreed with respect to two important principles concerning the doctrine of inquiry notice: First, does a plaintiff require specific information about all of the elements of the claim, and particularly scienter, before he may be said to have inquiry notice? Second, does the statute of limitations run from the point of initial notice that a violation may have occurred or from some undefined point thereafter, when the plaintiff has investigated his suspicions of fraud and collected sufficient information to file a suit?

Amicus WLF respectfully suggests that these questions may best be answered through a close consideration of the historical origins of the doctrine of inquiry notice.

1. The concept of inquiry notice has deep roots in the antecedents of the discovery rule established by the 1934 Act. The discovery rule emerged as a special equitable exception for fraud cases to the general rule that the statute of limitations would run from the time of the wrongful act. *See, e.g., Bailey v. Glover*, 88 U.S. 342, 347-50 (1874); *Stearns v. Page*, 48 U.S. 819, 829 (1849). When the defendant had perpetrated a fraud that could not have been detected before the expiration of the statute of limitations, "courts of equity will interpose and remove the bar out of the way of the injured party." *Stearns*, 48 U.S. at 829; *see also Bailey*, 88 U.S. at 350 (holding, in suits at law, that "the statute does not begin to run until the fraud is discovered by, or becomes known to, the party suing").

Because this discovery rule was an equitable exception to the important policies generally underlying the statute of limitations, nineteenth-century courts recognized that the plaintiff could only qualify for the exception by showing that he bore no responsibility for the delay in learning about the suit. *See Stearns*, 48 U.S. at 829. Thus, the party injured by the fraud was obliged to show that he remained "in ignorance of it without any fault or want of diligence or care on his part," *Bailey*, 88 U.S. at 348, and that "there has been no negligence or laches on the part of a plaintiff in coming to the knowledge of the fraud," *id.* at 349, such that "by the exercise of ordinary diligence, the discovery might not have been before made," *Stearns*, 48 U.S. at 829.

The concept of inquiry notice reflects the plaintiff's burden of showing that he exercised ordinary diligence by moving forward with his investigation at the first sign of the fraud. More than a century ago, courts recognized that a plaintiff placed on notice of a potential fraud would be charged with knowledge of all that he could have uncovered by pursuing a reasonable investigation into the matter. *See Wood v. Carpenter*, 101 U.S. 135, 141 (1879) ("Whatever notice is enough to excite attention and put the party on his guard and call for inquiry, is notice of every thing to which such inquiry might have led.").

Congress understood these principles when it codified the discovery rule in the 1934 Act, which this Court further relied upon in *Lampf*. In enacting an express discovery rule, Congress is presumed to have been aware of the underlying case law supporting the discovery rule. Indeed, the legislative history indicates Congress understood that the Act would incorporate the principles underlying the discovery rule, including inquiry notice.

2. Although the courts of appeals have agreed that the 1934 Act requires consideration of inquiry notice, they have disagreed over its application. This disagreement, however, arises principally because certain courts have applied these concepts without sufficient attention to their origins. Once inquiry notice is understood within its historical context, the specific standard to apply becomes clear.

First, a plaintiff does not require evidence of all elements of a fraud claim before he fairly has inquiry notice. The concept of inquiry notice arises out of the equitable principle of laches. *See Galliher v. Cadwell*, 145 U.S. 368, 373 (1892) ("laches is not, like limitation, a mere matter of time; but principally a

question of the inequity of permitting the claim to be enforced"). At equity, in cases of fraud, the question was whether the plaintiff had acted with reasonable diligence in investigating and pursuing his claim, such that he bore no blame for bringing a suit about long-ago events. *Bailey*, 88 U.S. at 348; *Wood*, 101 U.S. at 141.

Such equitable principles did not turn upon whether the plaintiff had received specific evidence of all elements of his claim, but whether he had received sufficient notice to create suspicion of a potential action. This reasoning was ultimately adopted in law. See Lyman Johnson, *Securities Fraud and the Mirage of Repose*, Wis. L. Rev. 607, 635 (1992) (laches would be applied in courts of law unless plaintiff's ignorance of fraud was "justifiable"). If a plaintiff has reason to suspect the existence of a cause of action, he has an obligation to move forward with an investigation. The plaintiff who ignores warning signs and does nothing should not get the benefit of additional time.

Second, in contrast to the holdings of some courts of appeals, the statute of limitations begins to run from the moment the plaintiff is on notice that a violation may have occurred, rather than the uncertain point when a reasonable investigation has or should have been completed. Once a plaintiff had notice of "storm warnings," rather than of all facts that would support a claim, the plaintiff would be charged with collecting any information that could be obtained through a reasonable investigation. *See Wood*, 101 U.S. at 141. The undisputed facts of this case show that the plaintiff here had such notice more than two years before filing suit.

3. This rule is necessary to prevent market manipulation, which may occur if investors use the delay as insurance against any unrelated decline in the price of a security—a situation courts have described as "[h]eads I win, tails you lose." *See, e.g., Tregenza v. Great Am. Commc'n Co.*, 12 F.3d 717, 722 (7th Cir. 1993). It would be inappropriate to allow the securities laws to be used as a conduit for speculation or a tool to minimize investment losses.

Further, inquiry notice makes sense because it is important both to plaintiffs and to defendants that the limitations period is established by a bright line rule. The limitations period should not depend upon a reviewing court's later determination of how long a "reasonable investigation" should have taken. Moreover, the purpose of the statute of limitations itself is not to permit a plaintiff to delay filing suit after he has uncovered all of the information necessary to bring a claim; rather, it is to give the plaintiff a reasonable time to move forward diligently to investigate the facts and prepare his claims.

ARGUMENT

I. THE LIMITATIONS PERIOD UNDER 28 U.S.C. § 1658(b) INCORPORATES THE COMMON LAW CONCEPT OF INQUIRY NOTICE

This case presents the Court with the opportunity to clarify when the limitations period begins to run for a securities fraud claim under section 10(b) of the Securities Exchange Act of 1934. When this Court first addressed the question of the applicable limitations period under section 10(b) in *Lampf,*

Pleva, Lipkind, Prupis & Petigrow v. Gilbertson, 501 U.S. 350, 359 (1991), the 1934 Act contained no express limitations period for such private claims because the cause of action under section 10(b) had been inferred by the courts, not expressly created in the statute. *See id.* at 358-59. The Court thus was obliged to perform the "awkward task" of determining what statute of limitations Congress would have set, had it foreseen that a private cause of action would be judicially recognized. *See id.*

In *Lampf*, the Court recognized that the 1934 Act itself contained the most analogous statute of limitations for implied actions under section 10(b). The statutes of limitations under the 1934 Act generally provided for a one-year period following the discovery of the violation combined with a three-year period of repose. The Court adopted a parallel framework under section 10(b) and, recognizing that provisions of the 1934 Act differed slightly in terminology, borrowed relevant language from section 9(e) of the Exchange Act, *id.* at 364, that "[n]o action shall be maintained to enforce any liability created under this section, unless brought within one year after the discovery of the facts constituting the violation and within three years after such violation." 15 U.S.C. § 78i(e).

In interpreting what constitutes "the discovery of the facts constituting the violation," the courts of appeals have uniformly concluded that this phrase constitutes a shorthand for the traditional application of the discovery rule. *See, e.g., Great Rivers Co-op. of S.E. Iowa v. Farmland Indus., Inc.*, 120 F.3d 893, 896 (8th Cir. 1997); *Tregenza v. Great Am. Communications Co.*, 12 F.3d 717, 721 (7th Cir. 1993); *Menowitz v. Brown*, 991 F.2d 36, 41 (2d Cir. 1993);

Howard v. Haddad, 962 F.2d 328, 330 (4th Cir. 1992) (Powell, J.); *Anixter v. Home-Stake Prod. Co.*, 939 F.2d 1420, 1434 (10th Cir. 1991). Under the discovery rule, as it has traditionally applied to fraud claims, the limitations period begins to run not only when the plaintiff obtains actual knowledge of the facts constituting the violation but also upon "inquiry notice," understood as "notice of the facts, which in the exercise of reasonable diligence, would have led to actual knowledge." *Menowitz*, 991 F.2d at 42.

In the Sarbanes-Oxley Act of 2002, Congress codified the statute of limitations for section 10(b) actions by adopting language identical to the *Lampf* standard but extending the period so that it would run for two years after discovery (and extending the period of repose to run for five years). *See* 28 U.S.C. § 1658(b). Insofar as Congress is presumed to be familiar with relevant judicial decisions, *see, e.g.*, *Cannon v. Univ. of Chicago*, 441 U.S. 677, 696-98 (1979), Congress's adoption of section 1658(b) is properly understood to have incorporated the courts' prevailing recognition of "inquiry notice" in federal securities law cases. "[I]n determining Congress's intent . . . we evaluate the state of the law when the Legislature passed [the law]." *Franklin v. Gwinnett County Pub. Sch.*, 503 U.S. 60, 71 (1992).

Although the courts of appeals have agreed on the relevance of "inquiry notice," they have differed on the specific standard to apply. The concept of inquiry notice, however, arises out of long-standing common law principles, and the disagreement among the courts of appeals reflects that certain courts, such as the Third Circuit below, have been insufficiently attentive to those foundational principles. A proper understanding of traditional inquiry notice

requires reversal of the decision before the Court at this time.

A. Historically, the Discovery Rule Has Been a Limited Exception to the Running of a Limitations Period

Statutes of limitations "are found and approved in all systems of enlightened jurisprudence." *Wood*, 101 U.S. at 139. Such limits have been applied for thousands of years. Ancient Hebrew, Roman, and early German and English law all recognized the importance of ending legal responsibility for most wrongs after some defined period of time. *See* David. G. Owen, *Special Defenses in Modern Products Liability Law*, 70 Mo. L. Rev. 1, 25 (2005).

Traditionally, a cause of action accrues—and the clock begins to run on a limitations period—when the wrongful act is committed and the injury occurs. 2 Calvin W. Corman, LIMITATIONS OF ACTIONS, § 11.1.1, at 134 (1991). In other words, the clock starts when the cause of action is complete. Statutes of limitations "represent pervasive legislative judgment that it is unjust to fail to put the adversary on notice to defend within a specified period of time and that the right to be free of stale claims *in time* comes to prevail over the right to prosecute them." *United States v. Kubrick*, 444 U.S. 111, 117 (1979) (emphasis added, internal quotations and citations omitted); *see also Stearns*, 48 U.S. at 828 ("Statutes of limitation form a part of the legislation of every government").

Despite the important and venerable policies underlying the statute of limitations, Anglo-American courts recognized a limited exception to the limita-

tions period for fraud cases where plaintiffs did not discover—and lacked a reasonable means of discovering—the injury until after the traditional statute of limitations had expired. This exception emerged first in cases at equity. Although the "lapse of time necessarily obscures the truth and destroys the evidence of past transactions," this Court recognized as early as 1849 that "if a party has perpetrated a fraud which has not been discovered till the statutable bar may apply to it in law, courts of equity will interpose and remove the bar out of the way of the injured party." *Stearns*, 48 U.S. at 829. The equitable solution was, in these instances, to postpone the commencement of the limitations clock until the plaintiff discovered, or at least had reason to discover, the cause of action. The Court later recognized that the rule would extend as well to actions at law. *See Kirby v. Lake Shore & M.S.R. Co.*, 120 U.S. 130, 138 (1887). A number of federal statutes of limitations now incorporate this discovery rule, either expressly or, in some cases, implicitly. *See TRW Inc. v. Andrews*, 534 U.S. 19, 27 (2001) (citing cases).[2]

B. Inquiry Notice Has Always Served to Limit the Discovery Rule

Just as the equitable discovery rule was well-established in the nineteenth century, so too was the

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[2] Equitable tolling as such is unnecessary in section 10(b) claims because the two-tiered structure of the limitations period applicable to such claims includes both a period that "by its terms, begins after discovery of the facts constituting the violation" and a second period that serves as a clear cutoff for all claims. *Lampf*, 501 U.S. at 363.

principle that later came to be known as inquiry notice. *See Bailey*, 88 U.S. at 347-50 ("when there has been no negligence or laches on the part of a plaintiff in coming to the knowledge of the fraud which is the foundation of the suit"); *Stearns*, 48 U.S. at 829 ("so that the court may clearly see, whether, by the exercise of ordinary diligence, the discovery might not have been before made"). Just as the discovery rule derives from equitable principles, its application was similarly limited by equitable concerns. This Court has recognized that statutes of limitations are, in part, designed to "punish negligence." *Wood*, 101 U.S. at 139. A plaintiff cannot prolong the limitations period indefinitely, because a court will not invoke its equitable powers if "fault or want of diligence or care on his part" kept the plaintiff in ignorance of his injury. *Bailey*, 88 U.S. at 348.

The discovery rule, as an exception to the commencement of the limitations clock, has historically been cabined by the inquiry notice concept. *Wood*, 101 U.S. at 141. A court would not exercise its inherent equitable power to delay the running of the limitations period unless the plaintiff had diligently undertaken an investigation of the facts at the time when questions were raised. Where "underlying frauds exist[] . . . it [is] his duty to make the effort [to unearth them]." *Wood*, 101 U.S. at 140; *Kirby*, 120 U.S. at 139 ("a court of equity will not be moved . . . after [the plaintiff] was put upon inquiry with the means of knowledge accessible to him"). A plaintiff who "fail[s] to make inquiry" deprives himself of the otherwise advantageous equitable exception to the limitations period. *United States v. Diamond Coal & Coke Co.*, 255 U.S. 323, 333 (1921).

The equitable principle of laches unquestionably underlies inquiry notice as a limitation upon the discovery rule. In *Bailey*, the Court explained that, in instances where "fraud has been concealed, or is of such character as to conceal itself," only "when there has been no negligence or laches on the part of a plaintiff in coming to knowledge of the fraud which is the foundation of the suit" will the court delay the commencement of the limitations period. 88 U.S. at 349-50. The courts look to laches as a guide when faced with questions regarding fraud that went undiscovered for long periods of time. *See Stearns*, 48 U.S. at 830.

Where the plaintiff seeks the benefit of the discovery rule, he must show "the time when the fraud . . . was discovered, and what the discovery is, so that the court may clearly see, whether, by the exercise of ordinary diligence, the discovery might not have been before made." *Id.* at 829. A plaintiff's ignorance must be justifiable. Courts therefore required plaintiffs to explain when and how particular discoveries were made so that the courts could examine "why it was not made sooner." *Wood*, 101 U.S. at 141. In this manner, a court could examine whether the plaintiff acted with reasonable diligence in investigating and pursuing his claim, and could ensure that the plaintiff bore no blame for a lengthy delay between the commission of the fraud and its discovery. *See Bailey*, 88 U.S. at 349.

Courts have long declined to assist those parties that for too long failed to act on their rights. A plaintiff who was unwilling to take the necessary action to

help himself cannot thereafter seek equitable help from the courts.[3]

C. The 1934 Act Incorporates These Established Historical Principles

In passing the Securities Exchange Act of 1934, Congress enacted various limitations provisions relevant to the present case. These include section 9(e), which applies to the regulation of brokers, and which includes the language relied upon by this Court in *Lampf*, requiring a claim to be brought "within one year after the discovery of the facts constituting the violation and within three years after such violation." 15 U.S.C. § 78i(e); *see Lampf*, 501 U.S. at 364.

Congress is presumed to have understood both the discovery rule and the principle of inquiry notice at the time it codified various statutes of limitations in the 1934 Act, including in section 9(e), and Congress is presumed to have been familiar with the relevant judicial decisions and to have legislated with that background in mind. *See, e.g., Cannon*, 441 U.S. at 696-98. "[I]n determining Congress' intent . . . we evaluate the state of the law when the Legislature passed [the law]." *Franklin*, 503 U.S. at 71.

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[3] Inquiry notice also finds root in nineteenth-century property law. A purchaser would not obtain good title if he had "constructive, or implied notice of an unregistered deed" or if he was "informed of any other fact, which would naturally put a careful and prudent man upon inquiry . . . in regard to the title, and he omit to pursue the inquiry." *Hart v. Farmers' & Mechanics' Bank*, 33 Vt. 252, 1860 WL 5019, at *8 (1860).

In addition to *Stearns*, *Bailey*, and *Wood*, described above, inquiry notice, as a limitation on the discovery rule, had been applied to securities fraud cases since at least 1894. In *Dorsey Machine Co. v. McCaffrey*, the Indiana Supreme Court observed "the decided weight of authority is in favor of the proposition that where a party has been injured by the fraud of another, . . . whereby the injured party remains in ignorance of it without any fault or *want of diligence on his part*, the bar of the statute does not begin to run until the fraud is discovered[.]" 38 N.E. 208, 211 (Ind. 1894) (emphasis added).

Legislative history shows that Members of Congress understood and anticipated that the discovery rule would apply under the 1934 Act's two-tiered statute of limitations. The Senate, while debating the adoption of the proposed limitations period, discussed that the Act was designed to address "another situation where it may take years to discover that a right of action has accrued." 78 Cong. Rec. 8201 (May 7, 1934) (remarks of Sen. Barkley), as well as the discovery rule's roots in state law. See 78 Cong. Rec. 8198 (May 7, 1934) (remarks of Sen. Byrnes) (under state law, actions for fraud "must be brought within 1 year after discovery of the statement").

The Senators were also aware of the concept of inquiry notice, its relevance to the language of section 9(e), and that the adoption of this language would start the clock as soon as a plaintiff suspected possible fraud. *See, e.g.*, 78 Cong. Rec. 8199 (May 7, 1934) (remarks of Sen. Kean) ("if a man buys something today and discovers tomorrow that some mistake has been made and *perhaps he has ground for a suit* because of fraud, under the terms of the bill he must bring his suit within one year") (emphasis

added). One of the legislation's detractors, Sen. George Norris of Nebraska, explicitly anticipated the application of inquiry notice when discussing its implications in the floor debates:

> Suppose . . . bonds are sold and that there is some fraud connected with their sale. Some of them are sold in California, and others are sold in Maine. The man in Maine discovers within a year that a fraud has been committed. He may commence suit in Maine, and 4 years later the man in California may commence suit. In either case the man does not know of the fraud until he himself discovers it. The man in California commences his suit within a year after he discovers the fraud; but the defense is that the case in Maine has given notice to the world of the alleged fraud, and that notice of it is bound to be taken in California and in every other place under the jurisdiction of our courts.

78 Cong. Rec. 8199 (May 7, 1934); *see also* 78 Cong. Rec. 8200 (May 7, 1934) (remarks of Sen. Norris) ("I think that in 9 cases out of 10, under this kind of statute, when they got to trial the question would arise whether the man had notice or whether he did not, what constituted notice, and how much he ought to have known about it."). Sen. Norris explained that he disfavored the pertinent language of section 9(e) because he feared that "[the statute of limitations] will date from the very beginning of [the plaintiff's] investigation. That will date from the very first

knowledge he had that there was anything wrong with the case." *Id.* at 8200-01 (May 7, 1934) (remarks of Sen. Norris). None of the Senators debating the 1934 Act expressed any disagreement with this interpretation of the text.

Thus, in approving the operative terms of section 9(e), and incorporating the two-tiered limitations period in the 1934 Act, Congress embraced the traditional discovery rule and required the same investigation and diligence on the part of investors that early cases had placed on plaintiffs alleging fraud. Congress further embraced the standard by retaining the same operative language in the recently enacted Sarbanes-Oxley section 1658(b), at issue here. *See, e.g.*, 148 Cong. Rec. 12, 502 (July 10, 2002) (statement of Sen. Leahy) (explaining that section 1658(b) would not change "the basic standards of the law").

II. TRADITIONAL PRINCIPLES OF INQUIRY NOTICE DETERMINE THE PROPER APPLICATION OF THE STATUTE OF LIMITATIONS TO THIS CASE

While this Court has long recognized a tension between two strong public policies—one favoring repose for events that occurred in the distant past, and another favoring merits-based disposition of legal claims—statutes of limitations represent a traditional legislative judgment that "the right to be free of stale claims in time comes to prevail over the right to prosecute them." *Kubrick*, 444 U.S. at 117. Limitations periods reflect "a value judgment concerning the point at which the interests in favor of protecting

valid claims are outweighed by the interests in prohibiting the prosecution of stale ones." *Johnson v. Ry. Express Agency, Inc.*, 421 U.S. 454, 463-64 (1975). The statute of limitations reflects a balance between discouraging fraudulent behavior and encouraging investor vigilance.

The same principles require the application of a reasonable inquiry notice standard to the question presented in this case. The standard adopted by the Third Circuit, that investors must receive notice of all elements of a fraud claim before the clock begins to run, prolongs the expiration of tardy securities fraud actions well beyond congressional intent. The commencement of the limitations period here must be determined with an eye toward the policies underlying the discovery rule. *See, e.g., Johnson* 421 U.S. at 463-64 ("Any period of limitation . . . is understood fully only in the context of the various circumstances that suspend it from running against a particular cause of action. . . . In virtually all statutes of limitations the chronological length of the limitation period is interrelated with provisions regarding tolling, revival, and questions of application.").

A. The Purposes of the Discovery Rule Are Best Served by the Application of Inquiry Notice without Reference to Scienter

A would-be plaintiff does not require notice of all facts that would support the pleading of the fraud claim before he or she is fairly viewed as having inquiry notice. *See Talmadge v. U.S. Shipping Bd., Emergency Fleet Corp.*, 54 F.2d 240, 243 (2d Cir. 1931) (L. Hand, J.) ("[T]he victim of the fraud shall

be put on notice of the practice upon him; he need not know the full details."). It is unreasonable to assume that a plaintiff will experience no true "storm warnings" until a hurricane actually makes landfall. *Betz v. Trainer Wortham & Co.*, 519 F.3d 863, 869 (9th Cir.) (Kozinski, J., dissenting from denial of rehearing en banc), *petition for cert. pending*, 76 USLW 3646 (2008).

Equitable principles did not turn upon whether the plaintiff had received specific evidence of all elements of his claim—only whether he had received sufficient notice to create the suspicion of a potential violation. "Whatever is notice enough to excite attention and put the party on his guard and call for inquiry, is notice of every thing to which such inquiry might have led. When a person has sufficient information to lead him to a fact, he shall be deemed conversant of it." *Wood*, 101 U.S. at 141 (quoting *Kennedy v. Greene*, 3 Myl. & K. 722). "There must be reasonable diligence; and the means of knowledge are the same thing in effect as knowledge itself." *Id.* at 143. If a plaintiff has reason to suspect the existence of a cause of action, he or she has an obligation to move forward with an investigation. *Wood*, 101 U.S. at 140 ("If underlying frauds existed, as he alleges, he did nothing to unearth them. It was his duty to make the effort."). Stalling the commencement of the limitations clock until a plaintiff has notice of each element rewards those plaintiffs who choose not to perform their equitable duties of reasonable diligence.

The Third Circuit's decision to require evidence of scienter does not find support in other areas of federal law where inquiry notice principles have been applied. This Court, in examining the judicially con-

structed limitations period for claims brought under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), has explained that "in applying a discovery accrual rule, we have been at pains to explain that discovery of the injury, not discovery of the other elements of a claim, is what starts the clock." *Rotella v. Wood,* 528 U.S. 549, 555 (2000); *see also Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 191 (1997). Similarly, in examining the Federal Tort Claims Act, the Court reasoned that the limitations period begins to run "at the point where the plaintiff . . . by the exercise of reasonable diligence should have been aware of" the "critical facts" of his injury. *Kubrick*, 444 U.S. at 122. In *Kubrick*, the Court rejected the argument that the applicable limitations period did not begin to run until the plaintiff knew that his injury was negligently inflicted, rather than at the time of the injury itself. *Id.* at 117–22.[4]

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[4] As this Court has recognized, "[w]here Congress uses terms that have accumulated settled meaning under . . . the common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of these terms." *See Field v. Mans*, 516 U.S. 59, 69 (1995). Similarly, courts in fraud cases arising under state law have construed comparable state statutes of limitations to run from the point when the plaintiff is on notice of the potentially false or misleading statement but lacks any information of scienter. The Eighth Circuit, surveying general principles of state law, held that "[e]vidence of scienter is usually circumstantial, and a defrauded victim will normally have only indicia of scienter before suing. Notice of the scienter element could not require knowledge of conclusive evidence, because conclusive evidence of scienter is rarely available, even through exercise of discovery. If that level of notice were required, the limitations period for fraud would never begin running." *Dummar v.*

B. Traditional Principles Require that the Limitations Period Begin to Run from Notice of "Storm Warnings"

Based on historical principles, and in contrast to the holdings of some courts of appeals, the limitations period properly begins to run from the moment the plaintiff has notice that a violation may have occurred, rather than from some uncertain point when a reasonable investigation has been, or should have been, completed. As the Second Circuit has observed, "not the time at which a plaintiff becomes aware of all of the various aspects of the alleged fraud, but rather the statute runs from the time at which plaintiff should have discovered the general fraudulent scheme. 'The statutory period does not await appellant's leisurely discovery of the full details of the alleged scheme.'" *Arneil v. Ramsey*, 550

Lummis, 543 F.3d 614, 620 (8th Cir. 2008) (quoting *City of Fairbanks v. Amoco Chem. Co.*, 952 P.2d 1173, 1179 (Alaska 1998)) (Nevada and Utah law). *See also Platt Elec. Supply, Inc. v. EOFF Elec., Inc.*, 522 F.3d 1049, 1059 (9th Cir. 2008) (California law); *Rodkey v. Capitol American Life Ins. Co.*, No. 93-35830, 42 F.3d 1401, 1994 WL 684506, at *3 (9th Cir. Dec. 7, 1994) (Montana law); *Nerman v. Alexander Grant & Co.*, 926 F.2d 717, 721-722 (8th Cir. 1991) (Missouri law); *Phillips v. Amoco Oil Co.*, 799 F.2d 1464, 1468-1469 (11th Cir. 1986) (Alabama law); *Pinkston v. Outdoor Equipment Distributors, Inc.*, No. 3:06cv222, 2007 WL 3028330, at *3-4 (W.D.N.C. Oct. 15, 2007) (North Carolina law); *Matthews v. Matthews*, 222 So. 2d 282, 284-286 (Fl. App. 2d Dist. 1969) (Florida law); *Shultz v. Manufacturers & Traders Trust Co.*, 40 F. Supp. 675, 686 (W.D.N.Y. 1941) (New York law).

F.2d 774, 780 (2d Cir. 1977) (internal citation omitted).

In traditional cases, once the plaintiff was on notice of sufficient "storm warnings," the plaintiff was charged at that time with any information that could be obtained through a reasonable investigation to support a claim. *Wood*, 101 U.S. at 141 ("When a person has sufficient information to lead him to a fact, he shall be deemed conversant of it."); *see also Go Computer, Inc. v. Microsoft Corp.*, 508 F.3d 170, 179 (4th Cir. 2007) ("And lest this seem too quick a trigger, it bears emphasis that the date of inquiry notice is not a filing deadline. It is only the date on which the cause of action accrues and the . . . period allotted by Congress for a plaintiff to investigate begins.").

In this case, there were sufficient "storm warnings" of potential fraud to motivate a reasonable investor to investigate, even without evidence of scienter or a drop in the price of Merck's stock. It is not disputed that on September 21, 2001, Merck shareholders learned that an agency of the federal government was alleging that Merck had engaged in a promotional campaign for Vioxx that misrepresented the drug's safety profile and failed to disclose key facts. Plaintiffs should have known from the Food and Drug Administration warning letter that putative false or misleading statements may have been harmful to their investment interests. Within a week of the posting of the letter, consumers had filed a class action alleging that Merck had engaged in fraud with respect to the marketing of Vioxx. Consumers of Merck's products were clearly on their guard and made further inquiry. Investors in Merck's securities should not, by alleging they lacked

notice of the element of scienter, be excused for their failure to move forward with their own investigation at the same point.

C. Public Policy Supports Application of Traditional Principles of Inquiry Notice to Resolve this Case in Favor of Petitioners

Adherence to the traditional principles of inquiry notice will prevent the potential for manipulation that would surely be invited by adopting the Third Circuit's approach. As the Seventh Circuit, per then-Chief Judge Posner, has explained:

> If the suspicious investor had a wide choice of times at which to sue within a three-year period rather than being required to sue no more than one year after the earliest possible date, the opportunistic use of federal securities law to protect investors against market risk would be magnified. These plaintiffs waited patiently to sue. If the stock rebounded from the cellar they would have investment profits, and if it stayed in the cellar they would have legal damages. Heads I win, tails you lose. This tactic is discouraged by the doctrine of inquiry notice . . . ."

Tregenza, 12 F.3d at 722. Otherwise, the Third Circuit's interpretation "would permit the securities acts to be used as havens for speculation and a buffer against any investment loss." *Cook v. Avien, Inc.*,

573 F.2d 685, 698 (1st Cir. 1978) ("[A]n investor cannot be allowed to wait for market increases knowing that if growth does not take place the securities acts will provide the insurance against loss."). The First Circuit in *Cook* correctly explained that "the exercise of reasonable diligence requires an investor to be reasonably cognizant of financial developments relating to this investment, and mandates that early steps be taken to appraise those facts which come to the investor's attention." *Id.*

There are also strong public policy interests supporting the conclusion that the limitations period should begin to run from notice of "storm warnings"—in other words, in the context of a fraud claim, from the point when the would-be plaintiff has notice of a potentially false or misleading statement or omission that may be harmful to the plaintiff but still lacks knowledge of all facts that would support the pleading of a claim, including evidence of scienter. The statute of limitations cannot depend upon the uncertain metric of a reviewing court's subsequent judgment of the appropriate duration of a "reasonable investigation."

There is no undue risk that if the Third Circuit's decision is reversed, plaintiffs will race to the courthouse at the smallest sign of danger. As extended by the Sarbanes-Oxley Act, the statute of limitations now provides a diligent investor with two years to complete a reasonable investigation and craft a sufficient complaint. Such two years from the point of inquiry notice should well be enough time for the diligent investor to uncover even complex securities fraud, ensuring that a reasonable investor would not be pressured to race to the courthouse prematurely.

Finally, inquiry notice will ultimately encourage business activity and protect investors. *See* Note, *Limitation Borrowing in Federal Courts*, 77 Mich. L. Rev. 1127, 1128-29 (1979). Just as statutes of limitations protect potential defendants from surprise lawsuits, inquiry notice avoids the chilling effect that a threat of litigation may have on business activities. The adoption of a clear standard for inquiry notice will remove an obstacle for companies seeking to assess their litigation risks more accurately and to insure them properly.

Capital markets cannot function efficiently if long-forgotten claims and allegations can be revived at any time in the far-flung future. Increased uncertainty about the future raises the cost of capital and otherwise skews incentives. In addition, inquiry notice protects the current investors in defendant companies. The shareholders depend on the financial health of their investments to secure their financial future. Without the reasonable limitations provided by a system of inquiry notice, the investors will ultimately bear the cost of defending stale litigation.

CONCLUSION

For the reasons explained, the judgment of the United States Court of Appeals for the Third Circuit should be reversed.

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